ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: July 30, 2023

ClinicalTrials.gov ID: NCT01856686

Study Identification

Unique Protocol ID:	Brain Proteins
Brief Title:	Neurocognitive and Neurobiological Improvement in ADHD Children by Modification of Dietary Protein (BrainProtein)
Official Title:	Neurocognitive and Neurobiological Improvement in ADHD Children by Modification of Dietary Protein
Secondary IDs:	

Study Status

Record Verification:	July 2023
Overall Status:	Completed
Study Start:	December 2013 []
Primary Completion:	June 2014 [Actual]
Study Completion:	July 2014 [Actual]

Sponsor/Collaborators

Sponsor:	Spanish Foundation for Neurometrics Development
Responsible Party:	Sponsor
Collaborators:	PronoKal Foundation Child Health Foundation

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 11/25/2013 Board Name: National Institutes of Health. Board Affiliation: Éthics Committee. Hosptial General Universitario de Elche. Alicante. Spain. Phone: 07513476185 Email: info@brainmech.org Address: Business First Liverpool. 25 Goodlass Road. L24 9HJ Liverpool, United Kingdom
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	Multicenter, Prospective, randomized, comparative and controlled study about the beneficial effects in behavior and brain connectivity of different dietary patterns in 100 children with ADHD between 7 and 12 years, followed up for 3 months of nutritional therapy.
Detailed Description:	The investigators collect electroencephalogram (EEG), event related potentials (ERP) data, and behavior parameters in ADD/ ADHD children that not take stimulants or other drugs during study. They would only follow some nutritional recommendations based on increasing the amount of dietary protein and fast carbohydrates decrease. The duration of the study will be 6 months, 3 months for recruitment and 3 months for dietary treatment.

Conditions

Conditions:	ADD ADHD
Keywords:	ADD ADHD Proteins Dietary Nutrition QEEG ERP

ICA

Study Design

Study Type:	Interventional
Primary Purpose:	Supportive Care
Study Phase:	Early Phase 1
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Single (Investigator)
Allocation:	Randomized
Enrollment:	64 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: BP22042013 This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.	Drug: BP22042013 This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. Other Names: • Brain Proteins Supplements
Experimental: Low carbohydrate Diet the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements	Dietary Supplement: Low carbohydrate diet the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements Other Names: • 2000 Kilo-calories without Fast Absorbing Carbohydrate

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	7 Years
Maximum Age:	13 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- ADHD diagnosed 12 months before
- no take medication
- BMI above the 25th percentile
- Wiesel score between 80 and 100 (about 120)
- Patients who agree to participate and whose guardians signed the informed consent form

Exclusion Criteria:

- eating disorders
- psychosis, bipolar disorder or depression
- kidney or liver failure
- diabetes
- diuretic or cortisone treatment
- haematological problems
- suprarenal diseases
- cancer
- Brain injury
- Cardiovascular or arrhythmia problems

Contacts/Locations

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Study Officials: Moises Aguilar-Domingo, PhD
Study Principal Investigator
Spanish Foundation for Neurometrics Development

Locations: **United Kingdom**
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Sub-Investigator: Fernando Vargas-Torcal, PhD

IPDSharing

Plan to Share IPD:

References

Citations:

Links: URL: http://www.deepbrain.uk
Description Brainmech Foundation

URL: http://www.fundacionsaludinfantil.org
Description Children Health Foundation

URL: http://www.fundacionpronokal.org/
Description Pronokal Foundation

Available IPD/Information:

Study Results

Participant Flow

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	This group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Overall Study

	BP22042013	Low Carbohydrate Diet
Started	31	33
Completed	26	22
Not Completed	5	11

	BP22042013	Low Carbohydrate Diet
Lost to Follow-up	5	11

Baseline Characteristics

Baseline Analysis Population Description

All patients without Electroencephalogram recordings at 3 months were excluded from statistical analysis.

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Baseline Measures

		BP22042013	Low Carbohydrate Diet	Total
Overall Number of Participants		26	22	48
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	26 participants	22 participants	48 participants
		9.08 (1.9)	9.41 (1.87)	9.23 (1.87)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	26 participants	22 participants	48 participants
	Female	10 38.46%	8 36.36%	18 37.5%
	Male	16 61.54%	14 63.64%	30 62.5%

		BP22042013	Low Carbohydrate Diet	Total
Reaction time [1] Mean (Standard Deviation) Unit of measure: milliseconds	Number Analyzed	26 participants	22 participants	48 participants
		520.46 (93.27)	506.59 (65.74)	514.10 (81.28)
		[1] Measure Description: Reaction time during visual continuous performance task from 19 channels EEG recordings		
Omission errors [1] Mean (Standard Deviation) Unit of measure: errors	Number Analyzed	26 participants	22 participants	48 participants
		19.31 (20.69)	18.00 (15.39)	18.71 (18.28)
		[1] Measure Description: omission errors during visual continuous performance task from 19 channels EEG recordings (test duration 22 minutes)		
Comission errors [1] Mean (Standard Deviation) Unit of measure: errors	Number Analyzed	26 participants	22 participants	48 participants
		4.58 (6.30)	2.82 (2.79)	3.77 (5.04)
		[1] Measure Description: Comission errors during visual continuous performance task from 19 channels EEG recordings (test duration 22 minutes)		
Occipital alpha waves-frequency [1] Mean (Standard Deviation) Unit of measure: Hz	Number Analyzed	26 participants	22 participants	48 participants
		9.62 (1.02)	9.48 (0.99)	9.55 (1.00)
		[1] Measure Description: Frequency Occipital alpha waves during visual continuous performance task		

		BP22042013	Low Carbohydrate Diet	Total
Occipital alpha waves-amplitude [1] Mean (Standard Deviation) Unit of measure: microvolts	Number Analyzed	26 participants	22 participants	48 participants
		15.75 (10.45)	20.56 (17.02)	17.95 (13.90)
		[1] Measure Description: Amplitude of occipital alpha waves during visual continuous performance task		
Parietal alpha waves-frequency [1] Mean (Standard Deviation) Unit of measure: Hertz	Number Analyzed	26 participants	22 participants	48 participants
		8.72 (1.04)	9.12 (0.94)	8.91 (1.00)
		[1] Measure Description: Frequency of Parietal alpha waves during visual continuous performance task		
Mu wave frequency [1] Mean (Standard Deviation) Unit of measure: Hertz	Number Analyzed	26 participants	22 participants	48 participants
		9.07 (1.22)	9.09 (1.06)	9.08 (1.14)
		[1] Measure Description: Frequency mu waves during visual continuous performance task		
Mu waves-amplitude [1] Mean (Standard Deviation) Unit of measure: microvolts	Number Analyzed	26 participants	22 participants	48 participants
		7.38 (6.77)	7.87 (8.09)	7.60 (7.33)
		[1] Measure Description: Amplitude of mu waves during visual continuous performance task		

		BP22042013	Low Carbohydrate Diet	Total
Frontal midline theta activity-frequency Mean (Standard Deviation) Unit of measure: Hertz	Number Analyzed	26 participants	22 participants	48 participants
		4.69 (1.13)	4.88 (1.40)	4.78 (1.25)
Frontal midline theta activity-amplitude Mean (Standard Deviation) Unit of measure: microvolts	Number Analyzed	26 participants	22 participants	48 participants
		8.08 (5.87)	11.66 (8.17)	9.72 (7.17)
Monastra ratio [1] Mean (Standard Deviation) Unit of measure: ratio	Number Analyzed	26 participants	22 participants	48 participants
		22.15 (8.75)	25.14 (9.72)	23.52 (9.23)
		[1] Measure Description: Theta wave/ Beta wave ratio		
weight Mean (Standard Deviation) Unit of measure: Kilograms	Number Analyzed	26 participants	22 participants	48 participants
		30.09 (7.66)	38.15 (11.36)	33.78 (10.26)
Body mass index Mean (Standard Deviation) Unit of measure: kg/m2	Number Analyzed	26 participants	22 participants	48 participants
		16.16 (2.87)	18.77 (3.66)	17.36 (3.48)

		BP22042013	Low Carbohydrate Diet	Total
Hyperactivity score (clinical scale) [1] Mean (Standard Deviation) Unit of measure: units on a scale	Number Analyzed	26 participants	22 participants	48 participants
		3.62 (2.59)	3.82 (2.67)	3.71 (2.60)
		[1] Measure Description: Hyperactivity score from clinical questionnaire. Range: minimum value: 0 and maximum value: 8. Higher values represent a worse outcome.		
Impulsivity score (clinical scale) [1] Mean (Standard Deviation) Unit of measure: units on a scale	Number Analyzed	26 participants	22 participants	48 participants
		4.58 (2.42)	4.82 (2.74)	4.69 (2.54)
		[1] Measure Description: Impulsivity score from clinical questionnaire. Range: minimum value: 0 and maximum value: 8. Higher values represent a worse outcome.		
Inattention score (clinical score) [1] Mean (Standard Deviation) Unit of measure: units on a scale	Number Analyzed	26 participants	22 participants	48 participants
		7.69 (1.52)	7.91 (1.60)	7.79 (1.54)
		[1] Measure Description: Inattention score from clinical questionnaire. Range: minimum value: 0 and maximum value: 9. Higher values represent a worse outcome.		
Behavior (clinical scale) [1] Mean (Standard Deviation) Unit of measure: units on a scale	Number Analyzed	26 participants	22 participants	48 participants
		15.88 (4.95)	16.55 (5.76)	16.19 (5.29)
		[1] Measure Description: Behavior assessed by total score of clinical questionnaire (sum of Hyperactivity, Impulsivity and Inattention scores). Range: minimum value: 0 and maximum value: 25. Higher values represent a worse outcome.		

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Reaction Time at 3 Months
Measure Description	Reaction time during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Reaction Time at 3 Months Mean (Standard Deviation) Unit of measure: milliseconds	506.58 (108.72)	510.59 (99.05)

Statistical Analysis 1 for Reaction Time at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.56593
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Reaction Time at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.44929
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Reaction Time at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.81844
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

2. Primary Outcome Measure:

Measure Title	Omission Errors at 3 Months
Measure Description	Omission errors during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach. (Test duration: 22 minutes)
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Omission Errors at 3 Months Mean (Standard Deviation) Unit of measure: errors	17.15 (19.54)	14.95 (13.43)

Statistical Analysis 1 for Omission Errors at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.71152
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Omission Errors at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.27795
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Omission Errors at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.47616
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

3. Primary Outcome Measure:

Measure Title	Comission Errors at 3 Months
Measure Description	comission errors during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.(Test duration: 22 minutes)
Time Frame	3 months

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Comission Errors at 3 Months Mean (Standard Deviation) Unit of measure: errors	2.19 (3.38)	2.82 (4.05)

Statistical Analysis 1 for Comission Errors at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.10036
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Comission Errors at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group changes

	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00820
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Comission Errors at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	1.00000
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

4. Primary Outcome Measure:

Measure Title	Occipital Alpha Brainwaves Amplitudes at 3 Months
Measure Description	occipital alpha waves amplitudes during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.

	Description
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Occipital Alpha Brainwaves Amplitudes at 3 Months Mean (Standard Deviation) Unit of measure: microvolts	12.25 (9.89)	11.99 (11.24)

Statistical Analysis 1 for Occipital Alpha Brainwaves Amplitudes at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.08946
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Occipital Alpha Brainwaves Amplitudes at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.27795
	Comments	[Not specified]

	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Occipital Alpha Brainwaves Amplitudes at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.01090
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

5. Primary Outcome Measure:

Measure Title	Mu Waves-amplitude at 3 Months
Measure Description	Mu waves-amplitude during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Mu Waves-amplitude at 3 Months Mean (Standard Deviation) Unit of measure: microvolts	6.32 (6.38)	6.05 (5.59)

Statistical Analysis 1 for Mu Waves-amplitude at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.05158
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Mu Waves-amplitude at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.94574
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Mu Waves-amplitude at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data

	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.09331
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

6. Primary Outcome Measure:

Measure Title	Frontal Midline Theta Activity- Amplitude at 3 Months
Measure Description	Frontal midline theta activity- amplitude during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Frontal Midline Theta Activity- Amplitude at 3 Months Mean (Standard Deviation) Unit of measure: microvolts	6.81 (3.62)	9.13 (7.30)

Statistical Analysis 1 for Frontal Midline Theta Activity- Amplitude at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.39707
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Frontal Midline Theta Activity- Amplitude at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.27945
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Frontal Midline Theta Activity- Amplitude at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.19739
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Occipital Alpha Waves-frequency at 3 Months
Measure Description	occipital alpha waves-frequency during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Occipital Alpha Waves-frequency at 3 Months Mean (Standard Deviation) Unit of measure: Hz	9.71 (1.13)	9.60 (1.24)

Statistical Analysis 1 for Occipital Alpha Waves-frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.92193
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Occipital Alpha Waves-frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.50704
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Occipital Alpha Waves-frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.42314
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

8. Secondary Outcome Measure:

Measure Title	Parietal Alpha Waves-frequency at 3 Months
Measure Description	Parietal alpha waves-frequency during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Parietal Alpha Waves-frequency at 3 Months Mean (Standard Deviation) Unit of measure: Hz	8.96 (1.09)	9.21 (1.07)

Statistical Analysis 1 for Parietal Alpha Waves-frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.73209
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Parietal Alpha Waves-frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.07965
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Parietal Alpha Waves-frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.61613
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Mu Wave Frequency at 3 Months
Measure Description	Mu wave frequency during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Mu Wave Frequency at 3 Months Mean (Standard Deviation) Unit of measure: Hz	9.06 (1.13)	9.07 (1.17)

Statistical Analysis 1 for Mu Wave Frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.94449
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Mu Wave Frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data

	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.94574
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Mu Wave Frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.85428
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Frontal Midline Theta Activity- Frequency at 3 Months
Measure Description	Frontal midline theta activity- frequency during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.

	Description
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Frontal Midline Theta Activity- Frequency at 3 Months Mean (Standard Deviation) Unit of measure: Hz	4.70 (1.38)	4.76 (1.30)

Statistical Analysis 1 for Frontal Midline Theta Activity- Frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.83929
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Frontal Midline Theta Activity- Frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.97213
	Comments	[Not specified]

	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Frontal Midline Theta Activity- Frequency at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.58323
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

11. Secondary Outcome Measure:

Measure Title	Monastra Ratio at 3 Months
Measure Description	Monastra ratio during visual continuous performance task from 19 channels EEG recordings, after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Monastra Ratio at 3 Months Mean (Standard Deviation) Unit of measure: ratio	16.88 (9.84)	22.36 (11.27)

Statistical Analysis 1 for Monastra Ratio at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.17383
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Monastra Ratio at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00092
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Monastra Ratio at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data

	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.15544
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

12. Secondary Outcome Measure:

Measure Title	Behavior
Measure Description	Behavior assessed by total score of clinical questionnaire (sum of Hyperactivity, Impulsivity and Inattention scores), after 3 months of nutritional approach. Range: minimum value: 0 and maximum value: 25. Higher values represent a worse outcome.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22

	BP22042013	Low Carbohydrate Diet
Behavior Mean (Standard Deviation) Unit of measure: units on a scale	13.08 (5.11)	12.45 (5.87)

Statistical Analysis 1 for Behavior

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.50964
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Behavior

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00710
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Behavior

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00595
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

13. Secondary Outcome Measure:

Measure Title	Hyperactivity Score
Measure Description	Hyperactivity assessed by clinical questionnaire after 3 months of nutritional approach. Range: minimum value: 0 and maximum value: 8. Higher values represent a worse outcome.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Hyperactivity Score Mean (Standard Deviation) Unit of measure: units on a scale	3.04 (2.39)	2.68 (2.25)

Statistical Analysis 1 for Hyperactivity Score

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.45013
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Hyperactivity Score

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.17374
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Hyperactivity Score

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.07548
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

14. Secondary Outcome Measure:

Measure Title	Impulsivity Score
Measure Description	Impulsivity assessed by clinical questionnaire after 3 months of nutritional approach. Range: minimum value: 0 and maximum value: 8. Higher values represent a worse outcome.
Time Frame	3 months

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Impulsivity Score Mean (Standard Deviation) Unit of measure: units on a scale	3.96 (2.16)	3.55 (2.22)

Statistical Analysis 1 for Impulsivity Score

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.23226
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Impulsivity Score

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.08812
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Impulsivity Score

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00776
	Comments	[Not specified]
	Method	Other [Pairedt-test]
	Comments	[Not specified]

15. Secondary Outcome Measure:

Measure Title	Inattention Score
Measure Description	Inattention assessed by clinical questionnaire after 3 months of nutritional approach. Range: minimum value: 0 and maximum value: 9. Higher values represent a worse outcome.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Inattention Score Mean (Standard Deviation) Unit of measure: units on a scale	6.08 (2.50)	6.23 (2.43)

Statistical Analysis 1 for Inattention Score

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.90843
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Inattention Score

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00413
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Inattention Score

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00775
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

16. Other Pre-specified Outcome Measure:

Measure Title	Weight at 3 Months
Measure Description	Weight after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Weight at 3 Months Mean (Standard Deviation) Unit of measure: kilograms	31.59 (7.28)	38.67 (11.18)

Statistical Analysis 1 for Weight at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.33027
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Weight at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data

	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.00013
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Weight at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.28019
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

17. Other Pre-specified Outcome Measure:

Measure Title	Body Mass Index at 3 Months
Measure Description	Body mass index after 3 months of dietary approach.
Time Frame	3 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.

	Description
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Body Mass Index at 3 Months Mean (Standard Deviation) Unit of measure: kg/m2	16.50 (2.54)	18.55 (3.43)

Statistical Analysis 1 for Body Mass Index at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013, Low Carbohydrate Diet
	Comments	Between-Group Comparison
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.48336
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Statistical Analysis 2 for Body Mass Index at 3 Months

Statistical Analysis Overview	Comparison Group Selection	BP22042013
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.08739
	Comments	[Not specified]

	Method	Other [Paired t-test]
	Comments	[Not specified]

Statistical Analysis 3 for Body Mass Index at 3 Months

Statistical Analysis Overview	Comparison Group Selection	Low Carbohydrate Diet
	Comments	Within-group comparisons between the baseline and 3 month data
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.37046
	Comments	[Not specified]
	Method	Other [Paired t-test]
	Comments	[Not specified]

18. Other Pre-specified Outcome Measure:

Measure Title	Number of Participants With Adverse Events as a Measure of Safety and Tolerability
Measure Description	Number of Participants with Adverse Events as a Measure of Safety and Tolerability of Brain Proteins Supplements
Time Frame	Up to 8 months

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

Measured Values

	BP22042013	Low Carbohydrate Diet
Overall Number of Participants Analyzed	26	22
Number of Participants With Adverse Events as a Measure of Safety and Tolerability Measure Type: Number Unit of measure: participants	0	0

Reported Adverse Events

Time Frame	3 months
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
BP22042013	This group of patients receive 2.000 kilocalories diet(60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes. BP22042013: This group of patients receive 2.000 kilo-calories diet (60 g. carbohydrates, 144 gr of fat and 107 gr of proteins), including 2 protein shakes.
Low Carbohydrate Diet	the second group of patients receive diet of 2.000 Kilo calories without rapidly absorbed carbohydrates and without proteins supplements Low carbohydrate diet: the second group of patients receive diet of 2.000 Kilo-calories without rapidly absorbed carbohydrates and without proteins supplements

All-Cause Mortality

	BP22042013	Low Carbohydrate Diet
	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/

Serious Adverse Events

	BP22042013	Low Carbohydrate Diet
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/26 (0%)	0/22 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	BP22042013	Low Carbohydrate Diet
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/26 (0%)	0/22 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

All Principal Investigators ARE employed by the organization sponsoring the study.

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