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

ClinicalTrials.gov ID: NCT04850703

Study Identification

Unique Protocol ID: 0104201UR

Brief Title: Brain Networks Implicated in Lifelong Premature Ejaculation Patients (LPE)

Official Title: Comparative Study of the Clinical Response Between tDCS and Dapoxetine, Define a Very Effective Therapeutic Target, That Improves the LPE in the Medium Long Term

Secondary IDs:

Study Status

Record Verification: July 2023

Overall Status: Completed

Study Start: February 2, 2021 [Actual]

Primary Completion: May 21, 2022 [Actual]

Study Completion: February 4, 2023 [Actual]

Sponsor/Collaborators

Sponsor: Spanish Foundation for Neurometrics Development

Responsible Party: Principal Investigator
Investigator: Moises Domingo [maguilar]
Official Title: Main Investigator
Affiliation: Spanish Foundation for Neurometrics Development

Collaborators:

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: U202110800 Board Name: Herefordshire Hospital Board Affiliation: European Association of Urology Phone: +44 7384039104 Email: abdul.harari@aol.com Address: Venns Lane, Hereford HR1 1DF
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	Using Brain Mapping and Cognitive ERPs, the investigatos have searched for a Brain Networks involved during Inhibitory Control in Lifelong Premature Ejaculation (LPE) participants. The investigators have designed a clinical trial comparing placebo with tDCS and blacebo group against Dapoxetine, studying the effects on LPE, as well as side effects and their medium and long-term duration.
Detailed Description:	Lifelong premature ejaculation (LPE) is a very common male sexual dysfunction like erectile dysfunction. It produces great distress to sexual harmony and even fertility. Previous neurophysiology studies revealed an ejaculation-related control mechanism in the brain: left inferior frontal gyrus (IFG) activation during successful inhibition. If we use the left IFG as a seed, participants showed weaker resting-state functional connectivity (FC) activity, between the seed and two areas (left dentate nucleus (DN) and right frontal pole) compared with controls. The main goal is to compare whether the brain biomarker only exists in participants with LPD and how it responds to treatment with Dapoxetine and with tDCS against the IFG networks and lDN, measuring the connectivity changes in these brain networks and FC.

Conditions

Conditions:	Premature Ejaculation Sexual Dysfunction
Keywords:	Brain Mapping EEG ERP tDCS tRNS Dapoxetine Lifelong premature ejaculation central inhibitory network function inferior frontal gyrus dentate nucleus right frontal pole Resting State Networks Funtional connectivity

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 1/Phase 2
Interventional Study Model:	Parallel Assignment Allocation: Randomized Intervention Model: Parallel Assignment
Number of Arms:	4
Masking:	Double (Care Provider, Investigator) 12 patients will be receive tRNS sham 10 sessions. 12 patients will take Dapoxetine, sham 10.
Allocation:	Randomized
Enrollment:	2021001 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Premature Ejaculation participants who receive Brain Weak Currents in IFG brain cortex Participants receive tRNS (weak currents < 2 mA) sessions at IFG brain cortex for 25 minutes 2 times a day 3 times per week during 3 weeks.	Device: Transcranial Radom Noise Stimulation tRNS against Dapoxetine in LPE patients Other Names:

Arms	Assigned Interventions
After 4 hours they end the last session, a new brain mapping is performed.	• tRNS
Active Comparator: Premature Ejaculation participants who take Dapoxetine Participants take 1 tablet of the drug between 1 and 3 hours before the brain mapping	Drug: Take Dapoxetine Dapoxetine against tRNS in LPE patients
Sham Comparator: Placebo Group Participants who do not take medication or receive tRNS sessions	Combination Product: Comparation EEG changes between Sham Group against tRNS and Dapoxetin participants Compare EEG parameters like Theta Rhythm and Coherence between three groups of participants: sham, tRNS participants and Dapoxetine participants groups.
Controls 44 Healthy humans not clinically not diagnosed with LPD and withouth expression the LPE endophenotype. In this way, the investigators what would be the patients diagnosed clinically with LPE who present the endophenotype or neurophysiological biomarker of LPE.	Diagnostic Test: Compare LPE EEG endophenotype between participants and healthy controls Define as precisely as possible the electrophysiological endophenotype of Longlife Premature Ejaculation, using healthy humans who do not express the LPE EEG endophenotype

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 30 Years

Maximum Age: 70 Years

Sex: Male

Gender Based: Yes
All of patients were diagnosed of Longlife Premature Ejaculation

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- To be over 18 years old and less than 70 years
- Best-practice diagnosed Longlife Premature ejaculation
- Diagnosed since at least one years prior to enrollment.
- No use drugs or medicines

Exclusion Criteria:

- Serious visual and hearing loss
- Brain injury following cranial trauma
- Other neurological disorders like Parkinson, ME, headache, etc.
- Birth trauma

- Mental retardation

Contacts/Locations

Central Contact Person: MOISES AGUILAR-DOMINGO, PhD
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Central Contact Backup: Jade Carpenter, Mrs
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Study Officials:

Locations: **United Kingdom**
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IPDSharing

Plan to Share IPD: No

References

Citations:

Links: URL: http://www.deepbrain.uk
Description Deepbrain Ltd

URL: http://herefordshireurology.co.uk/
Description Urology Department Hereford Hospital

Available IPD/Information:

Documents

Study Protocol
Document Date: January 24, 2021
Uploaded: 07/30/2023 14:16

Informed Consent Form
Document Date: January 24, 2022
Uploaded: 07/30/2023 15:08

Study Results

Participant Flow

Recruitment Details	Medical Laboratory
Pre-assignment Details	Telephone Interview 1 week before

Reporting Groups

	Description
Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Participants receive tRNS (weak currents < 2 mA) sessions at IFG brain cortex for 25 minutes 2 times a day 3 times per week during 3 weeks. After 4 hours they end the last session, a new brain mapping is performed. Transcranial Radom Noise Stimulation: tRNS against Dapoxetine in LPE patients
Premature Ejaculation Participants Who Take Dapoxetine	Participants take 1 tablet of the drug between 1 and 3 hours before the brain mapping Take Dapoxetine: Dapoxetine against tRNS in LPE patients
Placebo Group	Participants who do not take medication or receive tRNS sessions Comparation EEG changes between Sham Group against tRNS and Dapoxetin participants: Compare EEG parameters like Theta Rhythm and Coherence between three groups of participants: sham, tRNS participants and Dapoxetine participants groups.
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Overall Study

	Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls
Started	15	12	11	10
Completed	15	12	9	8
Not Completed	0	0	2	2

Baseline Characteristics

Reporting Groups

	Description
Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Participants receive tRNS (weak currents < 2 mA) sessions at IFG brain cortex for 25 minutes 2 times a day 3 times per week during 3 weeks. After 4 hours they end the last session, a new brain mapping is performed. Transcranial Radom Noise Stimulation: tRNS against Dapoxetine in LPE patients
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Baseline Measures

		Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls	Total
Overall Number of Participants		15	12	10	9	46
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	15 participants	12 participants	10 participants	9 participants	46 participants
	<=18 years	0 0%	0 0%	0 0%	0 0%	0 0%
	Between 18 and 65 years	14 93.33%	12 100%	9 90%	9 100%	44 95.65%
	>=65 years	1 6.67%	0 0%	1 10%	0 0%	2 4.35%
Age, Continuous Median (Standard Deviation) Unit of measure: months	Number Analyzed	15 participants	12 participants	10 participants	9 participants	46 participants
		44.24 (2.6)	45.44 (4.5)	38.9 (2.2)	39.4 (3.5)	39.0 (2.3)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	15 participants	12 participants	10 participants	9 participants	46 participants
	Female	0 0%	0 0%	0 0%	0 0%	0 0%
	Male	15 100%	12 100%	10 100%	9 100%	46 100%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	15 participants	12 participants	10 participants	9 participants	46 participants
	American Indian or Alaska Native	2 13.33%	1 8.33%	0 0%	1 11.11%	4 8.7%
	Asian	0 0%	0 0%	0 0%	0 0%	0 0%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%	0 0%	0 0%

		Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls	Total
	Black or African American	1 6.67%	2 16.67%	1 10%	0 0%	4 8.7%
	White	12 80%	9 75%	9 90%	8 88.89%	38 82.61%
	More than one race	0 0%	0 0%	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%	0 0%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	15 participants	12 participants	10 participants	9 participants	46 participants
United Kingdom		15	12	10	9	46
ERP latencies and Amplitudes Mean (Standard Deviation) Unit of measure: milliseconds	Number Analyzed	15 participants	12 participants	10 participants	9 participants	46 participants
CNV Latencies		225 (2.5)	250 (3.8)	220 (2.4)	200 (3.5)	224 (2.8)
CNV Amplitude		3.6 (46.2)	4.8 (39.5)	6.2 (29.5)	6.3 (30.0)	5.2 (36.3)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Wavelet Changes Define Brain Biomarker of LPE
Measure Description	The investigators will reported changes in wavelet (time-frequencies) in Left Prefrontal Lobe F3, F7 and Fz electrodes.
Time Frame	1 month

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
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Measured Values

	Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls
Overall Number of Participants Analyzed	15	12	10	9
Wavelet Changes Define Brain Biomarker of LPE Median (Standard Deviation) Unit of measure: Hertz	24 (44.0)	18.5 (27)	18 (26.5)	18.4 (26.8)

2. Primary Outcome Measure:

Measure Title	EEG Coherence Comparing Dapoxetine Against tRNS
Measure Description	The investigators will reported changes in brain connectivity comparing taking Dapoxetine with the use of tRNS, calculating EEG coherence.
Time Frame	2-3 months

Outcome Measure Data Not Reported

3. Primary Outcome Measure:

Measure Title	Adverse Events Comparing Dapoxetine Against tRNS
Measure Description	Report adverse events during the application of the protocol Dapoxetine / tRNS.
Time Frame	2-3 months

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Measure the Effect of Dapoxetine Through ERP Novelty Wave Comparing With the Values of the Controls
Measure Description	Changes in latencies and amplitude of Novelty wave in the Ventro-lateral prefrontal cortex comparing novelty wave in Dapoxetine group against controls.
Time Frame	1 month

Outcome Measure Data Not Reported

5. Secondary Outcome Measure:

Measure Title	Measure the Effect of tRNS Through ERP Novelty Wave Changes Comparing With the Values of the Controls
Measure Description	Changes in latencies and amplitude of Novelty wave in the Ventro-lateral prefrontal cortex comparing novelty wave in tRNS group against controls.
Time Frame	1 month

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	6 months
Adverse Event Reporting Description	Burning, Headache or dizzness

Reporting Groups

	Description
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All-Cause Mortality

	Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	0/0	0/0	0/0	0/0

Serious Adverse Events

	Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/0	0/0	0/0	0/0

Other Adverse Events

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

	Premature Ejaculation Participants Who Receive Brain Weak Currents in IFG Brain Cortex	Premature Ejaculation Participants Who Take Dapoxetine	Placebo Group	Controls
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/15 (0%)	0/12 (0%)	0/10 (0%)	0/9 (0%)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

Results Point of Contact:

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