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ClinicalTrials.gov ID: NCT06368726

Study Identification

Unique Protocol ID:	SFND04042024
Brief Title:	Result of tDCS in ASD Children With Comorbidities Like PANDAS, Rare Genetic Diseases or Autoimmune Disorders (tDCS&ASD)
Official Title:	Results of the Application of 80 Sessions of tDCS for 12 Months in Children Between 6 and 11 Years Old With Autism Spectrum Disorder With Rare Diseases, Genetic Problems or PANDAS
Secondary IDs:	

Study Status

Record Verification:	April 2024
Overall Status:	Enrolling by invitation
Study Start:	April 1, 2024 [Actual]
Primary Completion:	May 1, 2025 [Anticipated]
Study Completion:	July 1, 2025 [Anticipated]

Sponsor/Collaborators

Sponsor:	Spanish Foundation for Neurometrics Development
Responsible Party:	Sponsor
Collaborators:	Fundacion para la Salud Materno Infantil

Oversight

U.S. FDA-regulated Drug:	Yes
U.S. FDA-regulated Device:	Yes
Unapproved/Uncleared Device:	Yes
Post Prior to Approval/Clearance:	Yes
Pediatric Postmarket Surveillance:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 807.100 Serial Number: 1147 Has Expanded Access: Unknown
Human Subjects Review:	Board Status: Approved

Approval Number: LJMU02243001
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Data Monitoring: Yes

FDA Regulated Intervention: Yes

Section 801 Clinical Trial: Yes

Study Description

Brief Summary: Results of the application of 100 sessions of tDCS for 12 months in children between 6 and 11 years old with autism spectrum disorder with rare diseases, genetic problems or PANDAS

Detailed Description: tDCS will be applied to 90 children diagnosed with ASD with Mu activity in one of their two temporal lobes and to another 90 children tDCS will not be applied but rather conventional treatments such as the Denver method, etc., in addition to collecting their electroencephalograms in eyes open condition, evoked potentials will be performed. with Mismatch Negativity paradigm to calculate the P300 wave every 25 sessions with a rest of 5-6 weeks between every 25 sessions and the changes in voltage and frequency of the EEG will be analysed using FFT & PSD, as well as the latencies and amplitudes of its P300 wave.

Conditions

Conditions: Attention
Visual Perceptual Weakness
Social Behavior
Fluency Disorder
EEG With Periodic Abnormalities

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Study Model: Parallel Assignment
Two groups of childs: 90 childs receive tDCS treatment and 90 traditional treatments with Risperidone educational training, speech therapy and visual training.

Number of Arms: 2

Masking: Single (Investigator)

	Assessments regarding clinical recovery will be conducted by an assessor blind to treatment allocation.
Allocation:	Randomized
Enrollment:	180 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Traditional ASD approach The childs receive their tradicional interventions, Risperidone according to child's weight, diet, educational or speech therapies, pictographs.	Drug: Risperidone Risperidone Risperidone according to child's weighs Other Names: • Diet, educational or speech therapies, pictographs
Experimental: This group of childs will receive tDCS sessions This children receive 100 sessions during 12 monts in 4 groups of 25 sessions 2 per week of 30 minutes with a separation between them of at least 72 hours	Device: tDCS or Transcranial Direct Current Stimulation We use weak currents applied over the child's scalp over 30 minutes twice a week during 100 days Other Names: • tES Transcranial Electrical Stimulation

Outcome Measures

Primary Outcome Measure:

1. FFT
   Change in Voltage for every frequency band

   [Time Frame: 12 months]
2. Power Density Spectrum Changes or PSD
   Amplitude of the PSD

   [Time Frame: 12 Months]
3. ERP MMN changes
   Changes in P300 wave amplitude

   [Time Frame: 12 months]
4. ERP MMN Changes
   Changes in P300 wave latency

   [Time Frame: 12 Monts]

Secondary Outcome Measure:

5. Attention
   Using ATTC scale average Scale

   [Time Frame: 12 months]
6. Social Skills
   We used SSRS Scale Total Teacher Scale

   [Time Frame: 12 months]
7. Language
   GhostBusters Res Spoken Language and Listening Average Score from 40 Cards

   [Time Frame: 12 months]
8. Visual Contact

P200 wave amplitude in occipital lobe

[Time Frame: 12 months]

Eligibility

Minimum Age:	6 Years
Maximum Age:	11 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Age between 7 and 15 years old
- Diagnosis: PDD, ASD or PANDAS
- Have genetic alterations with geneticist reports like: mutation, random mating between organisms, random fertilization or crossing over (or recombination) between chromatids of homologous chromosomes during meiosis.
- Natural birth without caesarean or complications
- Normal Pregnancy

Exclusion Criteria:

- Head Trauma
- Brain Injuries like meningitis or encephalitis, including SaRS, Herpes or MERS infections
- Epilepsy
- Rare Diseases with Auto-Immune Disease
- Rare diseases with Endocrinology problems
- Fever or Biochemical problems in the First Blood Test (First Visit)
- Vaccines Reactions

Contacts/Locations

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IPDSharing

Plan to Share IPD: Undecided

NOTE : Plan to Share IPD must be 'Yes' or 'No' to satisfy ICMJE policy ('Undecided' is not accepted).

References

Citations: **[Study Results]** Moliadze V, Lyzhko E, Schmanke T, Andreas S, Freitag CM, Siniatchkin M. 1#mA cathodal tDCS shows excitatory effects in children and adolescents: Insights from TMS evoked N100 potential. Brain Res Bull. 2018 Jun;140:43-51. doi: 10.1016/j.brainresbull.2018.03.018. Epub 2018 Apr 3. PubMed 29625151

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