

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

ClinicalTrials.gov ID: NCT02662270

Study Identification

Unique Protocol ID: Fibromyalgia and TDCs
Brief Title: QEEG and Qualitative EEG for the Identification of Abnormal Patterns in Fibromyalgia Patients (QEEGFP)
Official Title: Quantitative and Qualitative EEG From Fibromyalgia Patients for the Identification of Abnormal Patterns on Closed Eyes EEG
Secondary IDs:

Study Status

Record Verification: July 2023
Overall Status: Completed
Study Start: March 1, 2022 [Actual]
Primary Completion: January 30, 2023 [Actual]
Study Completion: March 12, 2023 [Actual]

Sponsor/Collaborators

Sponsor: Spanish Foundation for Neurometrics Development
Responsible Party: Sponsor
Collaborators: Universidad de Murcia

Oversight

U.S. FDA-regulated Drug:
U.S. FDA-regulated Device:
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Approved
Approval Number: 11/11/2015
Board Name: Comité Ético de Investigación Clínica
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Data Monitoring: No

Study Description

Brief Summary: Fibromyalgia is a relatively young condition recently recognized by the WHO as a separated clinical entity. Part of the medical community thinks of it as a mixed condition between depression and rheumatic pain, however, functional data provided by sophisticated imaging techniques points at a diminished brain activity in several brain regions. The present study aims to characterize those findings by means of QEEG in order to establish the electroencephalographic characteristics of fibromyalgia patients.

Detailed Description: Fibromyalgia is a disease that part of the general population and even the medical community views with skepticism and only recently was accepted as a true condition by the World Health Organization. Some physicians see it as a form of depression mixed with rheumatic pain. However recent findings in functional magnetic resonance imaging and positron emitted tomography documented diminished brain activity on several regions. The impairments must be located within the areas with a documented functional defect, wherein, spontaneous braincells activity should arise. Therefore electroencephalography findings should be a valuable diagnostic tool for early detection in fibromyalgia. The present study aims to analyse the differences between bioelectric characteristics in EEG from fibromyalgia patients with their eyes closed in a 21 electrode arrangement. Normal graphoelements as well as abnormal ones and its topographic distribution and functional connections will be analyzed.

The working hypothesis is that fibromyalgia patients will present distinctive characteristics in the same areas where a diminished brain activity has been documented by metabolic and morphologic tests as a group and that those characteristics are suitable to be measured by QEEG and distinguishable from healthy subjects.

Conditions

Conditions: Fibromyalgia

Keywords: Fibromyalgia
QEEG
Brain activity
fMRI
Diagnosis

Study Design

Study Type: Observational

Observational Study Model: Case-Control

Time Perspective: Cross-Sectional

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 150 [Actual]

Number of Groups/Cohorts: 2

Groups and Interventions

Groups/Cohorts	Interventions
Cases Patients with a fibromyalgia diagnosis established according to the American College of Rheumatology current criteria by a trained physician.	
Controls Healthy subjects paired by age and gender to the subjects in the cases group.	

Outcome Measures

Primary Outcome Measure:

1. Differences between groups in Fast Fourier Transformation
Changes in Power in EEG over different electrodes
[Time Frame: Up to one year]
2. Topographic distribution of the frequency bands
Brain areas with a characteristic pattern
[Time Frame: Up to one year]
3. Dominant EEG frequency localization
To document the dominant frequency in the resting EEG for all subjects
[Time Frame: Up to one year]
4. Abnormal EEG-graphoelements description
To identify the abnormal EEG-graphoelements found in fibromyalgia patients
[Time Frame: Up to one year]
5. Functional connectivity
To identify the different brain connections between fibromyalgia patients
[Time Frame: Up to one year]

Eligibility

Study Population: Men and women between 20 and 70 years old divided in two groups, one consisting in 50 subjects diagnosed with fibromyalgia according to the current criteria of the American College of Rheumatology and a control group matched by age and gender without fibromyalgia

Sampling Method: Non-Probability Sample

Minimum Age: 20 Years

Maximum Age: 70 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- Men and women between 20 and 70 years old, diagnosed with fibromyalgia and a control group matched by age and gender

Exclusion Criteria:

Contacts/Locations

Central Contact Person: Moises Aguilar-Domingo, PhD
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Central Contact Backup:

Study Officials: Moises Aguilar-Domingo, PhD
Study Principal Investigator
Brainmech Foundation

Locations: **Spain**
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IPDSharing

Plan to Share IPD: Yes
Supporting Information:

Time Frame:
Access Criteria:
URL:

References

Citations: **[Study Results]** Branco J, Atalaia A, Paiva T. Sleep cycles and alpha-delta sleep in fibromyalgia syndrome. *J Rheumatol.* 1994 Jun;21(6):1113-7. PubMed 7932424

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[Study Results] Napadow V, Harris RE. What has functional connectivity and chemical neuroimaging in fibromyalgia taught us about the mechanisms and management of 'centralized' pain? *Arthritis Res Ther.* 2014;16(5):425. doi: 10.1186/s13075-014-0425-0. PubMed 25606591

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Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services