Trial record **6 of 9** for: Samuel Katsuyuki Shinjo

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tDCS in Post-Acute COVID-19 Patients With SARDs

ClinicalTrials.gov Identifier: NCT04890483

Recruitment Status : Recruiting
First Posted : May 18, 2021
Last Update Posted : May 18, 2021

See Contacts and Locations

Sponsor:
University of Sao Paulo

Information provided by (Responsible Party):
Samuel Katsuyuki Shinjo, PhD, University of Sao Paulo

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

Some patients develop "Post-acute COVID-19 syndrome," in which they experience persistent symptoms after recovering from the acute phase of COVID-19 infection. This syndrome may be more significant in

patients with systemic autoimmune rheumatic diseases (SARDs) who have been suffering from several symptoms associated to SARDs, such as myalgia, fatigue, and general pains.

The transcranial direct current stimulation (tDCS) technique has been frequent, for example, to relieve fatigue and general pains in general population. However, to date, there are no studies evaluating this technique in ARD patients with post-acute COVID-19; therefore, the main objective of the opened study is to evaluate the safety and efficacy of the application of acute tDCS in ARD patients with post-acute COVID-19.

Condition or disease	Intervention/treatment	Phase
Rheumatic Diseases Autoimmune Diseases	Device: Transcranial direct current stimulation	Not Applicable

Detailed Description:
Currently, there are no studies evaluating the tDCS technique in ARD patients with post-acute COVID-19; therefore, the main objective of the present study is to evaluate the safety and efficacy of the application of acute tDCS in these specific patients.

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
20 participants

Allocation:
N/A

Intervention Model:
Single Group Assignment

Intervention Model Description:
An open-label uncontrolled study of application of tDCS sessions in ARD patients with post-acute COVID-19.

Masking:
None (Open Label)

Primary Purpose:
Treatment

Official Title:
Transcranial Direct Current Stimulation in Post-Acute COVID-19 Patients With Systemic Autoimmune Rheumatic Diseases

Actual Study Start Date :

May 17, 2021

Actual Primary Completion Date :

May 17, 2021

Estimated Study Completion Date :

December 24, 2021

Resource links provided by the National Library of Medicine

MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019)

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Intervention The ARD patients with post-acute COVID-19 will receive tDCS sessions for one week.	Device: Transcranial direct current stimulation tDCS: the energy of the anode (transcranial current stimulation) will have as its source a battery-powered DC generator and will be exerted by two electrodes measuring 5x7cm and attached to the head. The electrodes will be located of the primary motor cortex. The electrode with positive charge (anode) will be positioned at contralateral to the dominant limb and the negative charged electrode will be positioned in the supraorbital region ipsilateral to the dominant limb. The active current of direct transcranial stimulation will be applied with the intensity of electric current of 2mA and density of 0.057 mA/cm2 with duration of 20 minutes. During the session, patients will remain seated. Number of sessions: five times, once per day.

Outcome Measures

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Primary Outcome Measures :

1. Frequency of treatment-emergent adverse events [safety and tolerability] [Time Frame: [Time Frame: After 30 minutes of transcranial stimulation.]]

   Frequency of disease relapsing (based on the questionnaire of secondary outcome measures) and tolerability (patients' symptom registration)

2. Frequency of treatment-emergent adverse events [safety and tolerability] [Time Frame: [Time Frame: After 5 sessions of transcranial stimulation.]]

   Frequency of disease relapsing (based on the questionnaire of secondary outcome measures) and tolerability (patients' symptom registration)

3. Frequency of treatment-emergent adverse events [safety and tolerability] [Time Frame: [Time Frame: After 30 days of transcranial stimulation.]]

   Frequency of disease relapsing (based on the questionnaire of secondary outcome measures) and tolerability (patients' symptom registration)

4. Frequency of treatment-emergent adverse events [safety and tolerability] [Time Frame: [Time Frame: After 60 days of transcranial stimulation.]]

   Frequency of disease relapsing (based on the questionnaire of secondary outcome measures) and tolerability (patients' symptom registration)

Secondary Outcome Measures :

1. Health Assessment Questionnaire (HAQ) [Time Frame: [Time Frame: 3 times: (a) within 30 minutes before stimulation. Then, after (b) one and (c) two months after stimulation]]

   Especific questionnaire (health assessment questionnaire). Pontuaction 0.00 (best) - 3.00 (worst)

Eligibility Criteria Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years to 80 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Patients with well-defined ARDs (rheumatoid arthritis, sclerosis systemic, Sjögren syndrome, spondyloarthritis, systemic lupus erythematosus, systemic vasculitis, and systemic autoimmune myopathies)
- Fatigue or general pains.

Exclusion Criteria:

- Neoplasia, using heart pacemarker, using visceral metalic clips, infections (HIV, HTLV-1, hepatitis), pregnance, previous historical of convulsions or epilepsies

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04890483***

Contacts

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Locations

Brazil

Samuel K **Shinjo** **Recruiting**

São Paulo, Brazil

Contact: **Samuel** K **Shinjo**, PhD 551130617176 ext 7176 samuel.shinjo@usp.br

Sponsors and Collaborators

University of Sao Paulo

Investigators

Principal Investigator: **Samuel** K **Shinjo**, PhD Sao Paulo University

More Information

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Responsible Party:

Samuel Katsuyuki Shinjo, PhD, Professor, PhD, University of Sao Paulo

ClinicalTrials.gov Identifier:

NCT04890483 History of Changes

Other Study ID Numbers:

MYO-HCFMUSP-09

First Posted:

May 18, 2021 Key Record Dates

Last Update Posted:

May 18, 2021

Last Verified:

May 2021

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Additional relevant MeSH terms:

Rheumatic Diseases
Collagen Diseases
Autoimmune Diseases
Musculoskeletal Diseases
Connective Tissue Diseases
Immune System Diseases