ISRCTN10844276 https://doi.org/10.1186/ISRCTN10844276

Clinical benefits of repeated cerebellar transcranial direct current stimulation sessions in Friedreich ataxia

Submission date
30/08/2023

Recruitment status
No longer recruiting

Registration date
07/09/2023

Overall study status
Completed

Last Edited
14/09/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Friedreich ataxia is a common type of ataxia (a neurological disorder affecting movement and coordination) that is passed down through genes. There's only one approved treatment for it in the United States. Scientists have discovered that using a type of brain stimulation called anodal cerebellar transcranial direct current stimulation (ctDCS) for one week can help reduce movement and thinking problems in people with Friedreich ataxia. In a study with a group of patients with cerebellar ataxia from mixed origin, doing this brain stimulation for more days (10 days instead of 5) in one go and then doing another round of it 12 weeks later can work even better for people with different kinds of ataxia. Now, researchers want to see if doing two rounds of 10 days of this brain stimulation, with a break of 12 weeks in between, is better than doing just one round of 10 days, followed by a fake stimulation session (sham) 12 weeks later. They want to figure out which approach improves movement and thinking problems in people with Friedreich ataxia more effectively.

Who can participate?
Patients with Friedreich ataxia who are aged over 14 to 100 years old

What does the study involve?
Patients will be randomly allocated to either two sessions of 10 days of anodal ctDCS (5 days /week for 2 weeks, 20 min/day, density current: 0.057 mA/cm2), separated by 12 weeks or one session of 10 days of anodal ctDCS followed by a sham ten days session 12 weeks later. Participants will be tested for improvement in their motor and cognitive symptoms in Friedreich Ataxia assessed by questionnaires.

What are the possible benefits and risks of participating?
A possible benefit is symptom improvement and risks are limited to local skin discomfort due to the ctDCS.

Where is the study run from?
HUB-Erasme Hospital (Belgium)

When is the study starting and how long is it expected to run for?
June 2021 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Gilles Naeije, gilles.naeije@hubruxelles.be (Belgium)

Contact information

Type(s)
Principal Investigator

Contact name
Prof Gilles Naeije

ORCID ID
http://orcid.org/0000-0003-1580-1970

Contact details
Service de Neurologie
HUB-Hôpital Erasme
808, Route de Lennik
Brussels
Belgium
1070
+3225558196
gilles.naeije@hubruxelles.be

Type(s)
Scientific

Contact name
Prof Gilles Naeije

Contact details
Service de Neurologie
HUB-Hôpital Erasme
808, Route de Lennik
Brussels
Belgium
1070
+3225558196
gilles.naeije@hubruxelles.be

Type(s)
Public

Contact name

Prof Gilles Naeije

Contact details
Service de Neurologie
HUB-Hôpital Erasme
808, Route de Lennik
Brussels
Belgium
1070
+3225558196
gilles.naeije@hubruxelles.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
B4062021000183

Study information

Scientific Title
Clinical benefits assessment of two sessions of 10 days of cerebellar transcranial direct current stimulation (ctDCS) against one ten days session of ctDCS in mitigating Friedreich ataxia cognitive and motor symptoms, a randomised sham controlled study

Study objectives
There is a benefit of repeating 10 days session of ctDCS for mitigating Friedreich Ataxia cognitive and motor symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/08/2021, Erasmus ULB University Hospital, Ethics Committee (Comite d'éthique Hospitalo-facultaire, Erasme-ULB) (808, route de Lennik, Brussels, 1070, Belgium; +3225553707; comite.ethique@erasme.ulb.ac.be), ref: P2021/347

Study design
Interventional randomized sham-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Friedreich ataxia

Interventions
This study will test whether two sessions of 10 days of anodal cerebellar transcranial direct current stimulation (ctDCS) given using a brain stimulator, 5 days/week for 2 weeks, 20 min/day, density current: 0.057 mA/cm2, separated by 12 weeks are more effective than one session of 10 days of anodal ctDCS followed by a sham ten days session 12 weeks later in improving motor and cognitive symptoms in Friedreich Ataxia. Motor and cognitive performances will be assessed by a neurologist using the SARA score for ataxic motor symptoms and the CCAS-S scale for cognitive symptoms before and after each session of stimulation. Improvement will be evaluated by computing the difference in the two scores before and after each session of stimulation. To allocate subjects to either sham or anodal ctDCS as second session, the Randperm(2) function of MatLab will be used.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Anodal transcranial direct current stimulation using a stimulator

Primary outcome measure
1. Motor symptoms measured using the Scale for the Assessment and Rating of Ataxia (SARA) before and after each stimulation session
2. Cognitive symptoms measured using the cerebellar cognitive affective syndrome scale (CCAS) before and after each stimulation session

Secondary outcome measures
Modification of resting state functional connectivity and brain fingerprints assessed by Magneto-encephalography recordings before and after ctDCS sessions

Overall study start date

01/06/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Patients with Friedreich ataxia
2. Aged > 14 to 100 years old

Participant type(s)
Patient

Age group
Mixed

Lower age limit
14 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
Intolerance to ctDCS

Date of first enrolment
04/09/2023

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Belgium

Canada

Study participating centre
HUB-Hôpital Erasme
808, route de Lennik

Bruxelles
Belgium
1070

Sponsor information

Organisation
Université Libre de Bruxelles

Sponsor details
CAMPUS ERASME
808, route de Lennik
Brussels
Belgium
1070
+3225556111
contact@erasme.ulb.ac.be

Sponsor type
University/education

Website
https://www.ulb.be

ROR
https://ror.org/01r9htc13

Funder(s)

Funder type
Government

Funder Name
Fonds De La Recherche Scientifique - FNRS

Alternative Name(s)
F.R.S. - FNRS, Fund for Scientific Research - FNRS, Belgian National Fund for Scientific Research, FNRS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Funder Name
Friedreich's Ataxia Research Alliance

Alternative Name(s)
FA Research Alliance, FARA

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Gilles Naeije (gilles.naeije@hubruxelles.be). These data will be anonymized SARA and CCAS-S results and will be available after completion of the study. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	17/08/2021	07/09/2023	No	Yes