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The ability of a new, non-invasive, combined treatment protocol to improve abnormal walking following stroke

Submission date
07/04/2021

Recruitment status
No longer recruiting

Registration date
14/04/2021

Overall study status
Completed

Last Edited
14/04/2022

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
During the year prior to the study, the Evexia Centre began a clinical evaluation of the potential for the combined therapy offered in TVMPS. Vibration stimulus to the skull proved to be able to identify brain damage sites. A static magnet complex, when placed on the skull over the identified area, was found to activate a specific pain response along either the arms or upper legs. This area on one of the limbs, when manipulated while the magnet complex was on the skull, was found to improve abnormal walking in stroke patients. This treatment was found to accelerate and improve the rehabilitation on these patients.
A new form of non-invasive brain stimulation diagnosis and therapy is being scientifically evaluated for its effect on post-stroke walking recovery.

Who can participate?
Patients aged 18 years and above who were referred to the Evexia Centre for stroke rehabilitation therapy could be included in the trial as long as they met the inclusion and exclusion requirements.

What does the study involve?
Those who were selected were randomly divided into two groups - one for fake and the other for real treatments. During 5-days, each group was measured for their ability to get up and go, rise up from a chair and sit again and with sophisticated walking parameters. In that same period, the placebo (fake) group received 3 fake treatments and the real group received 3 real treatments.

What are the possible benefits and risks of participating?
Since the methods used were non-invasive, no participant had risk of harm or bad side-effects. The possible benefit from the study results would be a better ability for stroke patients to recovery that is simple and cost-effective.

Where is the study run from?
Evexia Rehabilitation Centre (Greece)

When is the study starting and how long is it expected to run for?
August 2019 to July 2020

Who is funding the study?
Evexia Rehabilitation Centre (Greece)

Who is the main contact?
Joseph Shafer, therapy@evexia.com

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Post-stroke efficacy of transcranial vibration, magnetic and peripheral stimulation: a preliminary randomized controlled trial

Acronym
TVMPS

Study objectives
Post-stroke recovery efficacy of transcranial vibration, magnetic and peripheral stimulation as measured through gait outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2019, Evexia Rehabilitation Centre Ethics Committee (Thessaloniki-N.Moudania National Road, Nea Kallikrateia, 63080, Greece; +30 23990 76700; info@evexia.com), ref: 01.12.2019-001

Study design
Single center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Hemiparetic limb and gait recovery in patients with chronic unilateral cerebral hemispheric stroke

Interventions
Chronic stroke patients of the Evexa rehabilitation center agreed to participate in a controlled, gait outcome study. Through simple randomisation, participants were divided into placebo and treatment groups, each receiving either 3 sham or real treatments and 5 outcome parameter measurements. Seven measurement parameters - TUG, 5XSST, and Stride Velocity, Stride Length, Step Time, Stride Time and Cadence were measured on each of the trial days. Measurements were made, by staff who were unaware of participant group status, at the same time of day, prior to any sham or treatments.

Treatments consisted of imparting a transcranial vibration (TVS), through the use of a hand-held device, on the skull of the damaged hemisphere. Ipsilateral joint fixation capacity is simultaneously evaluated through a functional manual muscle test (fMMt). When TVS induces a fMMT failure, a static transcranial magnetic stimulation (sTMS) is made over the area and a peripheral stimulus zone (PSZ), located through a local pain response linked to the sTMS. The PSZ will either be on one of the arms or the upper legs and is located through a heightened pain-response that occurs with sTMS application to the skull. A treatment intervention is then made.

The Sham treatments consisted of placing the hand-held, non-vibrating device on the skull and having the patient perform a sham manual muscle test. Participants had no knowledge the methodology and had no interaction during the trial period. Seven standardised gait and movement outcomes were measured.

From trial onset to trial end was 5-days with day one as the baseline score and first real or sham treatment. On days two and four another sham or real treatment was made. Outcome measurements were made prior to treatment intervention on each of the five days.

Randomisation was a ‘simple coin flip’ where the coin was flipped 3-times and landed on its own. Two or more out of three flips was considered the choice.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
transcranial vibration (TVS)

Primary outcome measure

Measured at baseline, and daily for 5 days:
1. The timed up and go (TUG) test measures movement disorders related to gait and balance.
2. The five times sit to stand (5XSST) test is used to evaluate lower limb strength and falls risk through repetitive trials.
3. Instrumented gait (Kinesis Instrunmented Gait System) measurements of five gait parameters (stride and step times, stride velocity, stride length and cadence were measured.
TUG and 5XSST measurements are stand-alone and taken individually.
The gait parameters are statistically evaluated as individual elements and analysed with respect to their dynamic interaction.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2019

Completion date
30/07/2020

Eligibility

Key inclusion criteria
1. 18 years of age or older at time of presentation to the Evexia Centre for rehabilitation due to a right or left hemiparesis caused by a unilateral cerebral hemispheric stroke
2. A manifested a gait disorder, yet with the ability to ambulate (with or without a mobility aid) without assistance for at least 20 meters

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
17

Total final enrolment
15

Key exclusion criteria
1. Younger than 18 years old
2. No gait disorder
3. Inability to ambulate with or without mobility for 20 metres
4. Pacemaker, defibrillator and/or an intracerebral clip

5. Any cognitive deficit that could interfere with testing comprehension
6. Lower limb surgery less than 6 months prior to the study
7. Any concomitant, progressive or systemic disease.

Date of first enrolment
03/12/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Greece

Study participating centre
Evexia Rehabilitation Centre
National road Thessaloniki-N.Moudania
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Sponsor information

Organisation
Evexia Rehabilitation Centre

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Sponsor type
Hospital/treatment centre

Website
http://www.evexiahealthservices.com

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Evexia Rehabilitation Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary
Stored in repository