ISRCTN56839387 https://doi.org/10.1186/ISRCTN56839387

Evaluation of a mobile transcranial direct current stimulation device in chronic pain

Submission date
10/01/2014

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
11/01/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Neuropathic pain is a long-term condition that causes daily pain that cannot be relieved by normal painkillers. The aim of this study is to see if a particular form of brain stimulation called Transcranial Direct Current Stimulation (tDCS) can help reduce the level of pain in patients with this condition.

Who can participate?
Male and female patients aged between 18 and 85 who have previously taken part in a study using magnetic brain stimulation.

What does the study involve?
A small electric current is passed through the skull to affect the surface of the brain beneath. It does not require surgery and can be done by a compact and mobile device. Three treatments will be tested: active stimulation (anodal), reverse active stimulation (cathodal) and a placebo (dummy) stimulation. All patients will receive all three treatments over three different sessions in a random order. Each treatment session will last four weeks with a total of 12 weeks duration. We will test tDCS in these patients, who will include both responders and non-responders to the previous magnetic stimulation treatment, and compare their average pain scores before and after treatment.

What are the possible benefits and risks of participating?
The advantage, to those who respond to tDCS, is that it can be used at home and therefore reduces the number of hospital appointments needed, as well as the cost and inconvenience of travel to and from the hospital. There are very few risks and these are very minor, including temporary headache, minor skin irradiation and tiredness.

Where is the study run from?
The study is run from the Walton Centre NHS Foundation Trust (UK) and the Pain Research Institute in Liverpool, UK.

When is the study starting and how long is it expected to run for?
Recruitment started in September 2012. The study is expected to finish in May 2015.

Who is funding the study?
Royal College of Physicians and Surgeons of Glasgow, UK.

Who is the main contact?
Dr Francis ONeill
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Contact information

Type(s)
Scientific

Contact name
Dr Francis O'Neill

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UoL000869 RG030/12

Study information

Scientific Title
Evaluation of a mobile transcranial direct current stimulation device in chronic pain: a randomised controlled trial

Study objectives
It is hypothesised that in a group of chronic neuropathic pain patients, transcranial direct current stimulation to the contralateral motor cortex will improve levels of perceived pain as assessed on a numerical pain scale rating.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee East of England - Cambridge East, 17/07/2012, ref: 12/EE/0315

Study design
Randomised sham controlled double crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neuropathic pain

Interventions
Transcranial direct current stimulation delivered to the contralateral motor cortex. Two active stimulations and one sham stimulation will be given over three different treatment sessions in a randomised manner.

Active stimulations: anodal and cathodal 1.4 mA over 25 cm x 25 cm area for 20 min a day for 5 days each
Sham stimulation: current ramp for 30 seconds and then current off for the remaining 19.5 min

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Change in mean pain score as measured on a 0-10 point pain scale rating at baseline, and for two weeks starting on the first day of each treatment

Secondary outcome measures
1. Change in health-related quality of life SF-36
2. Change in anxiety or depression (HADS)
3. Global impression of change (GIC)
Secondary outcomes are measured at baseline and at 1 month following each treatment. Usually this equates to months 1, 2 and 3, unless the patient had any trouble attending a certain date.

Overall study start date

01/09/2012

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Age between 18-85 years old
2. Stable analgesic medication
3. Average pain levels >4 out of 10 on visual analogue scale (VAS) for pain during the one-week run-in phase, based on patient diary
4. Willingness to take part and ability to consent in study
5. Previously had a minimum of 5 sessions of TMS for pain, and can be named as a 'responder' or 'non-responder'. Responder: reporting a minimum pain reduction of 2 on a visual analogue scale (VAS) of 0-10, in at least 3 out of 5 rTMS sessions.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Severe pain of other origin (e.g., musculoskeletal pain) which in the opinion of the investigator may interfere with the reporting of the neuropathic pain being targeted
2. Metal implants/coils/electronic devices
3. Drug or alcohol abuse
4. Pregnancy
5. Psychiatric or psychological disorders
6. Epilepsy
7. Inability to understand instructions or operate equipment
8. Uncontrolled medical conditions (e.g., active cancer, uncontrolled renal, pulmonary or cardiac disease)

Date of first enrolment
01/09/2012

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Pain Research Institute
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
University of Liverpool/Walton Centre NHS Foundation Trust
3 Brownlow Street
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Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
Royal College of Physicians and Surgeons of Glasgow (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/04/2015		Yes	No
Results article	results	10/12/2018		Yes	No