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The influence of a non-invasive electrical stimulation over an area of the brain on pain and disability in patients with long-standing back pain

Submission date
18/01/2011

Recruitment status
No longer recruiting

Registration date
05/05/2011

Overall study status
Completed

Last Edited
02/06/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of anodal transcranial direct current stimulation (tDCS) in patients with chronic low back pain: a randomised controlled trial

Study objectives
The objectives of this study are to assess:
1. The effect of tDCS (5 consecutive days, once a day, 20 minutes, 2mA) on perceived pain intensity and disability of patients with non-specific CLBP (duration greater than 3 months)
2. The effect of tDCS given prior to a cognitive-behavioural group programme (standard care) on perceived pain and disability at the end of the programme

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Germany: Ethik-Kommission der Aerztekammer Hamburg approved on 04/01/2010, ref: PV3297. An amendment was approved on the 07/07/2010.
2. UK: Research Ethics Team of the University of Birmingham approved on 22/11/2010, ref: ERN_10-0863

Study design
Randomised sham-controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Chronic low back pain

Interventions
1. Both groups, verum and sham stimulation, will receive 20 minutes of tDCS on 5 consecutive days
2. Sham stimulation consists of a pre-programmed validated sham paradigm, verum stimulation

will be with an intensity of 2mA
3. Both groups will be followed-up after they have completed a 4 week group programme as well as 4, 12, 24 weeks after the last day of the programme

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Pain, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 100 = unbearable pain)
2. Disability, measured using the Oswestry Disability Index
3. Measurements at baseline, after tDCS period, after CBT, at 4 weeks, 12 weeks and 24 weeks post CBT

Secondary outcome measures
1. Subjective Functioning (Funktionsfragebogen Hannover)
2. Fear Avoidance Beliefs Questionnaire
3. Depression (Hospital Anxiety Depression Scale)
4. Quality of Life (SF 36)
5. Bothersomeness (5 point scale)
6. Patient Perceived Satisfactory Improvement (5 point scale)
Measurements at baseline, after tDCS period, after CBT, at 4 weeks, 12 weeks and 24 weeks post CBT.

Overall study start date
20/02/2011

Completion date
30/08/2012

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years, either sex
2. Categorised as suitable for a pain management programme
3. Have non-specific CLBP (with a minimum of 3 months of low back pain without any relevant ongoing pathologies such as acute disc prolapse, acute inflammation, bone fractures, spondylolisthesis or general health restrictions that require medical attention)
4. Are waiting to attend a cognitive behavioural group programme at a back pain clinic in North Germany
5. Provide written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
135

Key exclusion criteria
1. Other chronic pain syndromes
2. Spinal surgery in the past 6 month
3. Neurological disease
4. Psychiatric disease
5. Does not understand German
6. Pregnant or likely to become pregnant during the trial
7. Alcohol, drug, or medication abuse

Date of first enrolment
15/05/2011

Date of final enrolment
30/03/2013

Locations

Countries of recruitment
Germany

Study participating centre
Martinistr.52
Hamburg
Germany
20246

Sponsor information

Organisation
University Medical Center Hamburg-Eppendorf (Germany)

Sponsor details
c/o Mrs Kerstin Luedtke
Martinistr.52
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Germany
20246

Sponsor type

Hospital/treatment centre

Website
http://www.uke.de/

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

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?
Results article	results	16/04/2015		Yes	No