

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

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| Submission date 18/01/2011 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 05/05/2011 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 02/06/2015 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Other chronic pain syndromes
2. Spinal surgery in the past 6 months
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)

ROR

<https://ror.org/01zgy1s35>

Funder(s)

Funder type

Research council

Funder Name

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

Results and Publications

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 |