# 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	Recruitment status  No longer recruiting	[X] Prospectively registered		
18/01/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/05/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
02/06/2015	Musculoskeletal Diseases			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mrs Kerstin Luedtke

#### Contact details

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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 Hamburg 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