DRKS-ID: **DRKS00012292**
Date of Registration in DRKS: **2017/06/01**
Date of Registration in Partner Registry or other Primary Registry: **2017/05/31**

Trial Description

Title

Rehabilitating (stroke-induced) Apraxia with direct Current Stimulation

Trial Acronym

RAdiCS

URL of the trial

[---]*

Brief Summary in Lay Language

**After left cerebral stroke, besides the actual hemiparesis, a deficit of higher motor cognition is frequently observed: apraxia. Apraxic patients suffer from deficits of the execution of complex actions and gestures; deficits which cannot be explained by hemiparesis only.
The objective of the clinical trial is to investigate whether weak direct current stimulation can ameliorate apraxic deficits in the rehabilitation of stroke patients. Therefore, two electrodes are attached to the scalp and a weak current is applied over the lesioned hemisphere to increase brain activity after stroke. The treatment is conducted for 10 minutes at a time on five consecutive days. Additionally, motor tasks shall be performed before and after the stimulation. The weak direct current stimulation is compared to a sham stimulation (placebo). The participant is assigned randomly to the two study groups ('real' direct current stimulation or sham stimulation). The effect of the weak current stimulation on apraxia is measured 3-4 days after the last stimulation and after 3 months. Secondary outcome measurements (assessing motor functions) are likewise conducted 3-4 days after the last stimulation and after 3 months.**

Brief Summary in Scientific Language

Despite the high incidence of the motor cognitive deficit apraxia after left-hemispheric stroke, evidence-based therapies do not exist. This randomized controlled clinical trial (RCT) investigates whether anodal transcranial direct current stimulation (tDCS) as an add-on therapy during neuro-rehabilitation can ameliorate apraxia in left hemisphere stroke patients. Therefore anodal tDCS is applied over the parietal cortex of the left, lesioned hemisphere with an intensity of 2mA for 10 minutes at a time on five consecutive days. The treatment is combined with motor tasks before and after the stimulation. The effect of the stimulation is compared to a sham stimulation. Application of a pre-programmed study mode ensures a double-blind (patient and investigator) study design in regard to the applied stimulation (real tDCS versus sham). The primary endpoint is the apraxia score (KAS, Cologne Apraxia Screening) at 3-4 days after the last stimulation. A follow-up assessment is performed three months after the stimulation. Further outcome measurements - especially regarding motor function - are evaluated likewise after 3-4 days after the last stimulation and after 3 months.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012292**
- Date of Registration in DRKS: **2017/06/01**
- Date of Registration in Partner Registry or other Primary Registry: **2017/05/31**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **17-108 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1195-2536**
- Primary Registry-ID: **NCT03185234 (ClinicalTrials.gov)**

Health condition or Problem studied

- ICD10: **I63 - Cerebral infarction**
- Free text: **Apraxia after left hemisphere stroke**
- ICD10: **R48.2 - Apraxia**

Interventions/Observational Groups

- Arm 1: **Real tDCS: Anodal tDCS at an intensity of 2 mA is applied for 10 minutes at a time on 5 consecutive days. The anodal electrode is placed over the left parietal cortex (P3 in 10/20 EEG) of the lesioned hemisphere, the cathodal electrode is located supraorbital on the right side. Motor tasks are performed before and after the stimulation.**
- Arm 2: **Sham tDCS (placebo): Sham stimulation is applied for 10 minutes at a time on 5 consecutive days. One electrode is placed over the left parietal cortex (P3 in 10/20 EEG) of the lesioned hemisphere and a second electrode supraorbital on the right side. Motor tasks are performed before and after the stimulation.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Degree of apraxia, measured 3-4 days after the last stimulation (evaluated by KAS, Cologne Apraxia Screening), compared to baseline.

Secondary Outcome

In the post-interventional assessment 3-4 days after the last stimulation and after 3 months:

Degree of apraxia (measured by Goldenberg hand- and finger imitation; de Renzi imitation; de Renzi actual tool use),

Evaluation of strength (grip force vigorimeter; strength of hands by MRC-scale),

Extent of handicap (modified Ranking Scale, mRS),

Extent of aphasia (short version of Aphasia-Check-List).

After 3 months additionally:

Degree of apraxia (KAS, Cologne Apraxia Screening);

Movement function (Action Research Arm Test, ARAT; Jebsen-Taylor Hand Function Test, JTHFT).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Rehabilitationszentrum Godeshoehe e.V., Bonn**
- Medical Center **MediClin Fachklinik für Neurologie Rhein/Ruhr, Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/06/23**
- Target Sample Size: **110**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

Left hemispheric ischemic stroke in subacute/ chronic phase (>10 days and <180 days post-stroke);
Clinical confirmation of apraxia by KAS (Cologne Apraxia Screening), Cut-off ≤ 76/ 80 points;
Age 18 - 90 years;
written informed consent

Exclusion criteria

Pregnancy, breastfeeding and women without exclusion of pregnancy;
Patients with clinical manifestation of a stroke prior to the index-stroke;
malignant disease affecting the central nervous system;
epileptic seizure within the past two years;
life expectancy <12 months;
current addiction to alcohol or drugs or other addictive disease (exception: nicotine);
current clinically manifest psychiatric disorders, such as schizophrenia or severe depressive episode;
continuous medication during the intervention phase with benzodiazepine, antipsychotics of high potential and anti-epileptic drugs taken for prophylaxis of epileptic seizures;
enrollment in other studies with brain stimulation in the time period after the index-stroke;
heart pacemaker;
electrodes for deep brain stimulation or other metal implants in the head (expected are dental fillings and inlays); craniectomy or trepanation;
vulnerable skin lesions in electrode positions;
poor motivation/ cooperation

Addresses

■ **Primary Sponsor**

Universität zu Köln
50924 Köln
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

Klinik und Poliklinik für Neurologie, Uniklinik Köln
Mr. Univ.-Prof. Dr. med. Gereon R. Fink
Kerpener Str. 62
50924 Köln
Germany

Telephone: **0221-478-4000**
Fax: **[---]***
E-mail: **gereon.fink at uk-koeln.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik und Poliklinik für Neurologie, Uniklinik Köln
Ms. Dr. med. Nina Kleineberg
Kerpener Str. 62
50924 Köln
Germany

Telephone: **0221-478-98842**
Fax: **[---]***
E-mail: **nina.kleineberg at uk-koeln.de**
URL: **[---]***

■ **Contact for Public Queries**

Kognitive Neurologie, Klinik und Poliklinik für Neurologie, Uniklinik Köln
Mr. Prof. Dr. med. Peter H. Weiss-Blankenhorn
Kerpener Str. 62
50924 Köln
Germany

Telephone: **0221-478-98842**
Fax: **[---]***
E-mail: **peter.weiss-blankenhorn at uk-koeln.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik und Poliklinik für Neurologie, Uniklinik Köln,
Ms. Dr. med. Monika Richter
Kerpener Str. 62
50924 Köln
Germany

Telephone: **0221-478-98842**
Fax: **[---]***
E-mail: **monika.richter at uk-koeln.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik und Poliklinik für Neurologie, Uniklinik Köln,
Ms. Natalie Schloss
Kerpener Str. 62
50924 Köln
Germany

Telephone: **0221-478-98842**
Fax: **[---]***
E-mail: **nathalie.schloss at uk-koeln.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik und Poliklinik für Neurologie, Uniklinik Köln
Ms. Katharina Bolte
Kerpener Str. 62
50924 Köln
Germany

Telephone: **0221-427-98842**
Fax: **[---]***
E-mail: **katharina.bolte at uk-koeln.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Uniklinik Köln
Kerpener Str. 62
50924 Köln
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2021/11/09**
- Number of Participants in Germany after Recruiting complete: **117**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **117**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*