PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Comparing unilateral and bilateral computer-supported arm training for the severely affected arm after stroke

Trial Acronym

Arm motormed

URL of the trial

[---]*

Brief Summary in Lay Language

**We want to compare the effects of bilateral versus unilateral arm-cycle training on motor recovery in severely affected stroke patients.
Methods: 68 patients with a severe arm paresis are going to receive either unilateral or bilateral arm-cycle training. Both trainings are administered twice daily over six weeks and are followed by a repetitive hand training. Main outcome measures included the assessmants of hand function and biomechanical parameters (hand grip-, hand extension-, elbow flexion- and elbow extension isometric force) at the beginning, after 6 and 8 weeks.**

Brief Summary in Scientific Language

**Introduction: Functional recovery after stroke depends on brain plasticity. Ipsilesional and bihemispheric reorganization have been documented. In addition stroke patients experience an increased inhibitory influence from the contralesional to the ipsilesional motor cortex. Yet there is evidence that patients benefit from both bilateral and unilateral arm training. Therefore we want to compare the effects of bilateral versus unilateral computer-supported arm training on motor recovery in severely affected subacute stroke patients.
Methods: 68 patients with a severe arm paresis (Fugl-Meyer-Score for the arm (FMA) less than 18) are recruited for this randomized single-blinded study. The bilateral arm training entailes a repetitive training on an “arm-bicycle” followed by synchronized bilateral repetitive hand training. The unilateral arm training is identical but performed by the paretic limb only. Both trainings are administered twice daily over six weeks and incorporate shaping elements. Main outcome measures include the FMA and biomechanical parameters (hand grip-, hand extension-, elbow flexion- and elbow extension isometric force and rate of force generation), assessed at the beginning, after 6 and 8 weeks.**

Organizational Data

- DRKS-ID: **DRKS00009294**
- Date of Registration in DRKS: **2016/01/28**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **224-08 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- Free text: **Infarct in the MCA territory**
- ICD10: **I63.5 - Cerebral infarction due to unspecified occlusion or stenosis of cerebral arteries**

Interventions/Observational Groups

- Arm 1: **Group 1: 6 weeks of bilateral repetitive arm training on an "arm-bicycle" , twice a day for 20 minutes each followed once-a-day synchronized bilateral repetitive hand training, on 5 days per week**
- Arm 2: **Group 2: 6 weeks of unilteral repetitive arm training on an "arm-bicycle" , twice a day for 20 minutes each, followed once-a-day by unilateral repetitive hand training, on 5 days per week**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Change of Fugl-Meyr-Sccore will be measured 6 and 8 weeks post inclusion

Secondary Outcome

biomechanical Parameter such as
1. hand extension force (isometric),
2. Rate of rise of tension of hand extension force,
3. elbow flexion and extension force (at an angle of 60degrees, isometric),
4. hand grip force
5. Rate of rise of tension of hand grip force,
will be recorded at T0, T6 and T8

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **NRZ Bennewitz, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/01/30**
- Target Sample Size: **68**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

first ever Stroke of MCA (middle cerebral artery)
severe Paresis of upper extremity, 0-2 BMRC (british medical Research council),
Fugle-meyr-Score<18

Exclusion criteria

Aphasia, previous strokes, other neurologic disease, Spasticity of the arm, shoulder pain on affected side

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

NRZ Leipzig-Bennewitz,Universität Leipzig
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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/10/01**

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.*