Trial Description

Title

Upper limb strength training in subacute stroke patients. A randomized controlled trial.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This study´s objective is to investigate the savety and the effectiveness of a resistance arm training in subacute stroke patients. We will separate patients into two groups. Group 1 will receive (additionally to standard therapy) an intensive upper limb strength training with rising resistances. Group 2 will receive (additionally to standard therapy) a functional arm training with a rising number of repetitions. Training will be performed for 3 weeks. Patients will be examined before and directly after training for arm function, activities of daily living and participatory goals. Side effects will be systematically recorded.

Brief Summary in Scientific Language

Prospective two-armed randomized controlled trail; pre-post-design
Subacute stroke patients will be randomized into two groups:
intervention group: intensive upper limb strength training with rising resistances;
Control group: functional arm training with increasing repetitions
Training will be performed 3 times per week for 3 weeks.
Measures: T0 baseline, T1 post-treatment, primary outcome is grip strength, side effects will be systematically recorded in the training protocol
Patients and assessors are blinded for group affiliation

Organizational Data

- DRKS-ID: **DRKS00012484**
- Date of Registration in DRKS: **2017/05/26**
- 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.: **23/3/17 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **I60 - Subarachnoid haemorrhage**
- ICD10: **I61 - Intracerebral haemorrhage**
- ICD10: **I62 - Other nontraumatic intracranial haemorrhage**
- ICD10: **I63 - Cerebral infarction**
- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- Free text: **stroke**

Interventions/Observational Groups

- Arm 1: **Additionally to standard therapy, group 1 receives an intensive upper limb strength training with an intensity of 80 % of the maximum force (determined with the 1RM = one repetition maximum). It is a sixty-minute circuit training, 3 times per week, for 3 weeks (a total of nine training units). It includes five standardized functional exercises, performed in three series, each with about 10 repetitions. The resting time between the exercises and series is 120 seconds. The resting time between training units is 24 hours. The training includes unilateral, active and functional exercises. Heavy objects and elastic bands are used to rise resistances systematically. The standard rehabilitation for the arm includes mobilization, stretching, arm and hand motor training, strengthening exercises, robot- and device-supported function training and activity training.**
- Arm 2: **Additionally to standard therapy, group 1 receives a functional arm training with an intensity of 40 % of the maximum force (determined with the 1RM = one repetition maximum). It is a sixty-minute circuit training, 3 times per week, for 3 weeks (a total of nine training units). It includes five standardized functional exercises (the same as in group 1), performed in three series, each with about 10 repetitions. The resting time between the exercises and series is 120 seconds. The resting time between training units is 24 hours. The training includes unilateral, active and functional exercises. Objects or elastic bands must be gripped and moved over different distances. During training the number of repetitions increased - from initially ten to 18 in the last training unit (in each training one repetition is added). The standard rehabilitation for the arm includes mobilization, stretching, arm and hand motor training, strengthening exercises, robot- and device-supported function training and activity training.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor**
- 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

The primary endpoint is grip strength. It is measured by a hand-held dynamometer (unit: kilogram). The measurement takes place immediately before and after the three weeks of training.

Secondary Outcome

The Upper Extremity Fugl-Meyer assessment (0 to 66 points) measures sensorimotor impairments.

The Box & Block Test assesses the dexterity of arm activities. The number of cubes successfully transported in one minute (0 – 150 pieces) will be documented.

Motricity Index (0 – 100 points) measures upper extremity strength of representative arm movements after stroke

With the Goal Attainment Scale, individual goals of the patient can be evaluated in a standardized way. The attainment of participatory goals is assessed with a five-stage scale (-2 to +2 points).

The Modified Ashworth Scale (0 - 5 points) measures changes in muscle tone and reflex activity.

The measurement takes place immediately before and after the three weeks of training.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Asklepios Kliniken Schildautal Seesen, Klinik für Neurologische Rehabilitation, Seesen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/05/29**
- Target Sample Size: **78**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Subacute stroke patients with a Barthel Index > 29
Sitting Balance Score greater than or equal to 2
ability to put the paretic arm from the lap on a table
Medical Research Council score of 2 - 4 in shoulder abduction, elbow flexion or finger flexion
Passive range of motion: shoulder abduction, flexion and elbow flexion at least 90 °, touch of the fingers with the thumb, submaximal finger extension
Apraxia Screen of TULIA score of at least 5

Exclusion criteria

4 points on the Modified Ashworth Scale
pain of the affected arm with greater than 5 points on a pain scale
armparesis caused of other neuromuscular or neurological disorders and / or syndromes
manifest hereditary diseases (Such as cardiac insufficiency (> NYHA 1), angina pectoris, myocardial infarction within 120 days before the beginning of the study, cardiomyopathy, hypertension (WHO grade 2 systole 160-179 mmHg and diastole 100-109 mmHg) or difficultly controllable cardiac arrhythmia)
inflammation or infections that are associated with fever, bad condition, or insulation

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2018/05/01**

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.*