

## Trial Description

### Title

**Use of the robotic asissted hand therapy system Manovo®Power in patients with a stroke**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**In this study will be investigated the intra and inter reliability with the grip strength measurement Manovo®Power.  
Also will be evaluated the satisfaction of the patients and practiability of the device in the therapists point of view**

### Brief Summary in Scientific Language

**In this study will be investigated the intra and inter reliability with the grip strength measurement Manovo®Power.  
Also will be evaluated the satisfaction of the patients and practiability of the Devise in the therapists point of view**

## Organizational Data

- DRKS-ID: **DRKS00009010**
- Date of Registration in DRKS: **2015/08/07**
- Date of Registration in Partner Registry or other Primary Registry: **2015/08/03**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EKSG 15/078 , Ethikkommission Sankt - Gallen (Schweiz)**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Impairment of the upper extremity after CVI**

## Interventions/Observational Groups

- Arm 1: **grip strength measurement**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]\***
- Who is blinded: **[---]\***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Investigating the intrater and interater - reliability of the Manovo®Power measuring Hand strength.**  
**the Manovo®Power is a tool used to measure Hand strength.**  
**The Biometrics E- Link Hand grip Dynamometer is a measuring tool to measure Hand strength.**  
**The Hand strenght will be measured with the Manovo®Power on 2 days in the morning with an interval of 2-3 days inbetween (example: Mo-We-Fr or We-Fr-Mo)**  
**The Hand strenght will also be measured with the Biometrics E- Link Hand grip Dynamometer on 2 days in the afternoon with an interval of 2-3 days inbetween (example: Mo-We-Fr or We-Fr-Mo)**

## Secondary Outcome

**Investigating the correlation between the Manovo®Power assessment and Biometrics E-Link Hand grip Dynamometer.**  
**Therby, a third measurement will be performed.**  
**Evaluation on patients satisfaction and practicality from the therapist's point of view. The questionnaire will be specially developed to evaluate the patient's satisfaction, respectively the practcality of use.**

## Countries of recruitment

- **CH Switzerland**

## Locations of Recruitment

- Medical Center **Klinik für Neurologie und Neurorehabilitation, Kliniken Valens, 7317 Valens**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/08/10**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **95 Years**

## Additional Inclusion Criteria

**patients after stroke, primary event < 24 months, no additional diagnosis, which the treatment for improving the hand and arm function is negatively influenced.  
age  $\geq 18$**

**A degree of active arm/ Hand function (Chedoke-McMaster Stroke Assessment: handstadium:  
2-7)**

**passive range of Motion**

**shoulder: Flexion/ABD  $\geq 60^\circ$**

**elbow: Deficit of extension  $\leq 30^\circ$**

**hand wrist: extension  $\geq 0^\circ$**

**fingerextension: ability to open the hand half way**

**ability to communicate in German language plus enough speech comprehension and appropriate cognitive abilities to implement simple tasks**

**written informed consent**

## Exclusion criteria

**severe sensory loss (NIH-Stroke**

**Scale: sensibility(arm) = 2 points (no surface and deep sensibility)**

**shoulder pain (Chedoke shoulder - pain  $\geq 5$ )**

**severe/ global aphasia**

**epilepsy**

## Addresses

### ■ Primary Sponsor

**Klinik für Neurologie und Neurorehabilitation  
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### ■ Contact for Scientific Queries

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## Sources of Monetary or Material Support

### ■ Private sponsorship (foundations, study societies, etc.)

**Stiftung Valens und Walenstadtberg  
Taminaplatz 1  
7317 Valens  
Mr. Professor Jürg Kesselring**

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## Status

- Recruitment Status: **Recruiting planned**
- Study Closing (LPLV): **[---]\***

## 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.