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

## Trial Description

### Title

**Influence of two different concepts for positioning on passive range of motion, comfort and vital parameters in severely affected patients with CNS lesion**

### Trial Acronym

**[---]***

### URL of the trial

**http://lin-arge.de**

### Brief Summary in Lay Language

**Positioning is required in patients with lesions in the central nervous system due to prevention of pressure sore, comfort and influence on vital parameters. There is currently little evidence.
In Germany the positioning procedure is quite homogeneous – conventional positioning. In addition there is a newly developed positioning procedure – LiN-positioning in neutral.
Aim of the study is to find out which influence can be found on the above-named parameters. In a multicentre setting severely affected patients, who for example have had a stroke, hypoxia or head trauma, are positioned randomly, allocated to the different positioning procedures. Measurement of passive range of motion, comfort and some vital parameters are taken before and after being positioned for two hours. LiN is considered to be more beneficial .**

### Brief Summary in Scientific Language

**RCT, multicentre, blinded
200 patients will be enrolled**

## Organizational Data

- DRKS-ID: **DRKS00004163**
- Date of Registration in DRKS: **2012/06/11**
- 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.: **2008-115-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- ICD10: **G93.1 - Anoxic brain damage, not elsewhere classified**
- ICD10: **G31 - Other degenerative diseases of nervous system, not elsewhere classified**
- ICD10: **G35 - Multiple sclerosis**
- ICD10: **S06 - Intracranial injury**

## Interventions/Observational Groups

- Arm 1: **Positioning in LiN-Positioning in Neutral for two hours**
- Arm 2: **Positioning in conventional for two hours**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**difference of degrees of passive range of motion of flexion of the hip joints before and after being positioned for two hours**

### Secondary Outcome

**difference of degrees of passive range of motion of flexion and external rotation of the**

**shoulder joints,**
**bloodpressure,**
**pulse,**
**breathing frequence**
**before and after lying for two hours,**
**comfort measured with a 3-step visual rating scale after lying for  hours**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Medical Center **Phase-B-Rehazentrum, Neresheim**
- Medical Center **Therapiezentrum, Burgau**
- Medical Center **neurologische Rehabilitationsklinik, Bad Neustadt**
- Medical Center **Johanniter Ordenshäuser, Bad Oeynhausen**
- University Medical Center **Intensivbereich, Bonn**
- Medical Center **Geriatrie, Lingen**
- other **St. Georg Phase F, Leipzig**
- Medical Center **Prosperkrankenhaus Geriatrie, Recklinghausen**
- Medical Center **neurologische Rehabilitationsklinik, Kipfenberg**
- Medical Center **St. Bernwardkrankenhaus, Hildesheim**
- Medical Center **Marienkrankenhaus, St. Wendel**
- Medical Center **Krankenhaus Jockgrim, Jockgrimm**
- Medical Center **Neuroreha Klinikum Bremen Ost, Bremen**
- Medical Center **KKEL-Gelsenkirchen Resse-Phase F, Gelsenkirchen**
- Medical Center **KKEL-St. Barbara-Gladbeck, Gladbeck**
- Medical Center **SWH Karl Borromäus, Abt. Langzeitbeatmung und Weaning, Linz**
- Medical Center **Rehabilitationsklinik Geriatrie, Telgte**
- Medical Center **KKH Gummersbach, Klinikum Oberberg GmbH, Gummersbach**
- Medical Center **Rheinische Kliniken Bonn, Bonn**
- Medical Center **BGU-Murnau, Murnau**
- Medical Center **Klinikum Saarbrücken, Saarbrücken**

## Recruitment

-

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2011/04/04**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

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

### Additional Inclusion Criteria

**lesion of the central nervous system,**
**4 and 5 on the rankin scale scored from 0-5**

### Exclusion criteria

**contractures**
**life-threatening health condition**

## Addresses

- **Primary Sponsor**

**Medizinische Hochschule Hannover**
**Klinik für Neurologie**
**Bereich Bewegungsstörungen**
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■ **Contact for Scientific Queries**

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## Sources of Monetary or Material Support

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

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- **Private sponsorship (foundations, study societies, etc.)**

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E-mail: **hpickenbrock at gmail.com**
URL: **www.lin-arge.de**

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/09/30**

## Trial Publications, Results and other documents

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