Trial Description

Title

Rehabilitation of impaired body orientation in space: investigation of responsivity of the Spacecurl as a measuring instrument

Trial Acronym

IFB 1b

URL of the trial

[---]*

Brief Summary in Lay Language

A substantial proportion of stroke syndromes are associated with deficits in body perception. This includes impairments of balance and spatial orientation. Most patients with impaired balance tilt to both the right and the left side of the body as well as forward or backward. Some patients not only tilt to the side, but actively push to the paralyzed side, even when a therapist tries to correct the oblique body position. This disturbance is known as pusher syndrome. Another impairment of spatial orientation is the neglect. Neglect means that the patient ignores one side.

Previous studies found a positive effect of robot-assisted gait training with the Lokomat on the pusher syndrome and of galvanic vestibular stimulation on neglect.
For the diagnosis of body perception disorders mainly clinical scales are available so far.
In this study we will conduct additional examinations using a medical device for the determination of body orientation in space (Spacecurl).
We will investigate whether the therapy effects can also be measured with the Spacecurl.

Based on this clinical trial we hope to improve our understanding of the different body perception disorders and become able to diagnose and treat them more accurately.

As part of this clinical trial Spacecurl, galvanic vestibular stimulation (GVS) and Lokomat are used. These certified medical devices are already in use in neurological rehabilitation.

The Spacecurl is a purely mechanical system for the three-dimensional medical training therapy. It consists of three concentric rings and the subject stands in the centre of the apparatus on a platform that is attached to the three rings. The Spacecurl allows a rotation in all three dimensions with a full range of motion (360 °). The 3 rings of the Spacecurl are separately lockable and thus the movement can be restricted to a single plane. When releasing all rings any desired motion can be performed. The Spacecurl is used only by trained persons. For the study, the patients are tilted passively with a maximum of 25 ° from the vertical.

10 patients with pusher syndrome will undergo a session Lokomat therapy and a

**session conventional physiotherapy within one week. 10 patients with neglect will perform 3 units galvanic vestibular stimulation within one week.
Immediately before and after each treatment body orientation will be tested on the Spacecurl. The patient is tilted to the left, right, backwards and forwards by the examiner and slowly directed back to the middle.**

**To control the effect of the therapies, following diagnostic measures will be assessed additionally:
(1) To verify pusher symptoms: Scale for contraversive Pushing and lateropulsion-scale
To verify neglect symptoms: neuropsychological tests
(2) The measurement of subjective visual vertical (SVV) and subjective haptic vertical (SHV). The SVV is measured with a bucket having a straight line on the bottom. The bucket is rotated slowly and the patient indicates when he perceives the line as vertical and not tilted sideways.
The SHV is measured using a stick fixed on a board.The patient closes his eyes and turns the stick in a vertical position**

**Time schedule pusher arm:
Day 0: Screening
Day 1: Lokomat and day 3: conventional physiotherapy OR
Day 1: conventional physiotherapy and day 3: Lokomat**

**Time schedule neglect arm:
Day 0: Screening
Day 1, 3 and 5: GVS: cathode left OR right OR sham stimulation (pseudorandomized)**

Brief Summary in Scientific Language

**The aim of this study is to proof the responsiveness of the Spacecurl as an assessment instrument and therefore to determine the sensitivity to small changes.
Cerebrovascular-related brain injuries often lead to disturbances of balance and spatial orientation. Clinically relevant syndromes are neglect (failure of spatial orientation in the horizontal/axial plane with neglect of visual objects in the (usually left) visual field and adjustment of the subjective visual vertical normally to the right), retropulsion (disturbance of spatial orientation in the sagittal/pitch plane with shift of the center of mass to posterior) and pushing (disturbance of spatial orientation in the coronal plane with a shift of the center gravity to the plegic side). Distinct forms of these disorders hamper the rehabilitation process and can result in injuries (e.g. falls or accidents). Therefore the use of appropriate diagnostic and rehabilitative methods is necessary and objective of this project.**

While vestibular patients show deviations in the subjective visual vertical (SVV) patients with pusher syndrome seem to have an affected subjective postural vertical (SPV) (Paci et al. 2009). To date the SPV has been measured only in seating position. The Spacecurl allows to measure the SPV in standing position, in both the coronary and sagittal plane. Although brain lesions and the normal aging process are often associated with an affection to fall backward, the sagittal plane was largely neglected in previous studies. Barbieri et al. (2010) found a body vertical tilted backwards for older people while seated. Cardoen & Santens (2010) described the "Posterior Pusher Syndrome".

The perception of body orientation is determined by the integration of vestibular, somatosensory and visual signals. Depending on the sensory channels involved, a disorder can affect the perception of the subjective visual or postural vertical.

The ability to estimate the vertical is also dependent on context and cognition (Guenther et al. 2009). The direction of earth-vertical is underestimated at large tilt angles and overestimated at small angles (Jaggi-Schwarz and Hess, 2003).

Rao et al. (2010) found in stroke patients on a tilted platform an approximately 3 times worse perception of body position than in healthy control subjects. Many patients after right-hemispheric stroke also show both neglect and pusher symptoms (Pérennou 2006). SVV and SPV measurements of the same patient were carried out so far only in sitting position and the coronal plane.

From our start-up project we know that GVS in patients with neglect and the Lokomat in patients with pusher symptoms leads to a clinically significant improvement in their symptoms. These improvements should also be apparent in the Spacecurl measurements.

10 patients with pusher syndrome receive one session conventional physiotherapy and one session Lokomat therapy in a pseudo-randomized order, whereas 10 patients with neglect receive three units galvanic vestibular stimulation (GVS - cathode left, anode right, sham stimulation). Immediately before and after each therapy session the subjective postural vertical (SPV) is assessed using the Spacecurl.

Time schedule pusher arm:
Day 0: Screening
Day 1: Lokomat + Day 3: conventional physiotherapy OR
Day 1: conventional physiotherapy + Day 3: Lokomat

time schedule neglect arm:
Day 0: Screening
Day 1, 3 and 5: GVS, cathode left OR right OR sham stimulation

The order of treatments varies and is pseudo-randomized, that means each study participant will receive any form of stimulation. To minimize potential transfer or learning effects, the allocation of the possible sequence of treatments is balanced. I.e. almost every possible sequence occurs with equal frequency.

Blinding: Blinding of the patients is only possible in the application of different stimulation parameters during GVS, but not for the comparison of conventional physiotherapy and Lokomat therapy. The diagnostic assessments are performed by a blinded rater.

The Spacecurl is a purely mechanical system for the three-dimensional medical training therapy. It consists of three concentric rings and the subject stands in the centre of the apparatus on a platform that is attached to the three rings. The spacecurl allows a rotation in all three dimensions with a full range of motion (360°).
The 3 rings of the Spacecurl are separately lockable and thus the movement can be restricted to a single plane. When releasing all rings any desired motion can be performed. The Spacecurl is used only by trained persons. For the study, the patients are tilted passively with a maximum of 25 ° from the vertical.

Organizational Data

- DRKS-ID: **DRKS00003228**
- Date of Registration in DRKS: **2011/11/08**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Date of Registration in DRKS: **2011/11/08**
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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **405/11 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

- Other Secondary-ID: **DRKS00003212 (Diese Studie ist Teilprojekt 1 a unter der EK-Nummer 405/11. This study is subproject 1a within the EC-ID 405/11.)**
- Other Secondary-ID: **DRKS00003444 (Diese Studie ist Teilprojekt 2 unter der EK-Nummer 405/11. This study is subproject 2 within the EC-ID 405/11.)**

Health condition or Problem studied

- ICD10: **I69.3 - Sequelae of cerebral infarction**
- ICD10: **R27 - Other lack of coordination**
- ICD10: **R29.5 - [generalization R29: Other symptoms and signs involving the nervous and musculoskeletal systems]**
- ICD10: **R29.3 - Abnormal posture**

Interventions/Observational Groups

- Arm 1: **10 patients with unilateral right-hemispherical stroke and pusher symptoms receive 1 conventional physiotherapy unit and 1 Lokomat therapy unit in pseudo-randomized order, i.e. conventional physiotherapy at day one and Lokomat therapy at day three or vice versa. The actual time of therapy is about 20 minutes for both therapies, however 10 additional minuts are needed before and after the Lokomat therapy for entering and exiting the Lokomat. Before and after each therapy unit the SPV (subjective postural vertical) is measured in the Spacecurl.**

  The Lokomat is a motor-driven orthosis. A fall during the therapy session is not possible because the patient is suspended in a harness system. Only when entering and exiting the Lokomat there is a theoretical risk of falling. This is negligible because the patient can be driven in the wheelchair on the treadmill and the harness system can be put on and saved in sitting position. The Lokomat offers the patient the opportunity to be treaten for an extended period in a vertical body position. In our start-up project we could show that a already a single therapy session on the Lokomat has an immediate positive influence on pusher behaviour.
- Arm 2: **10 patients with unilateral right-hemispheric stroke and neglect**

symptoms receive three units of (galvanic vestibular stimulation) GVS (cathode left, cathode right, sham stimulation at day 1, 3 and 5 in a pseudo-randomized order). Before and after each therapy session, the SPV is measured in the Spacecurl.

Stimulation procedure: The electrodes are placed in saline-moistened viscose sponge pouches. This is to avoid skin irritation caused by electrolysis as well as to improve conductivity. The electrodes are placed behind the ear on the mastoid on both sides. In one stimulation scenario (left cathodal) the anode is placed behind the right ear and the cathode behind the left ear, in the second condition (right-cathodal) the sides are changed. The electrodes on the head are fixed with a bandage.

The two active stimulation scenarios are carried out with direct current under the detection threshold. The detection threshold is defined as follows: the device is turned on (green indicator light is active). The adjusting knob is rotated stepwise, whereby the intensity of current is slowly increased until the patient reports a slight tingling sensation under the electrodes. Then the current is slowly reduced until the patient notices no more tingling. The threshold determination is repeated for the verification of the threshold value.

In the sham stimulation, the electrodes are placed in the same way. The device is also switched on, so that the indicator light turns green. However, there is no current flow because the intensity of current is turned up no more than 0 mA.

The device is placed out of sight of the patient at all stimulation scenarios. The duration of stimulation is 20 minutes.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Active control**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Measurement of Subjective Postural Vertical (SPV) before and after the respective intervention (Pusher (arm 1): day1 and day 3, Neglect (arm 2): day 1, day 3 and day 5.

The SPV is measured with the Spacecurl. The examiner slightly tilts the subject in the Spacecurl (coronal and sagittal plane) and leads him slowly (1.8 °/s) back to the vertical. The subject beckons to the investigator (verbally or by pressing a

button) when he feels vertically aligned. He also has the possibility to self-adjust his position to the vertical (magnitude estimation and magnitude production). The degrees are measured on a calibrated scale affixed on the Spacecurl. In addition, they are recorded by a Accelometer, which contains a gyroscope.

Secondary Outcome

Measurement of Subjective visual vertical (SVV) and Haptic Subjective Vertica (SHP) before and after the respective intervention (Pusher (arm 1): day 1 and day 3, Neglect (arm 2): day 1, day 3 and day 5).

Subjective visual vertical (SVV)
The bucket method was evaluated by Zwergal et al. (2009) as an easily performed and reliable bed-side test to measure the SVV. For the assessment the subject sits upright and looks into a bucket. The visual field is completely covered by the edge of the bucket. On the bottom of the bucket is a dark, straight line. The bucket is rotated slowly by the examiner from different starting positions in the direction of zero position. The subject indicates when he determines the dark line as vertical and the investigator reads out the deviation in degrees on a scale on the outside of the bucket.

Haptic Subjective Vertical (SHP)
The SHP is measured with a stick affixed on a vertical board . The subject turns it with his eyes closed from various starting positions in the position where they guess the stick is vertically. Deviation from the vertical can be read out in degrees on a scale on the board.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/02/01**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

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Minimum Age: **18 Years**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Patients with unilateral right-hemispherical stroke and pusher or neglect symptoms
- Patient is able to be in upright body position for at least 30 min (for arm 1)

Exclusion criteria

Exclusion criteria for the Spacecurl (arm 1 and 2 affected):
• Severe cardiovascular disorders
• known thrombosis
• known Aneurysms
• unstable spine
• neurosis / psychosis
• advanced pregnancy
• body height below 145 cm and over 195 cm or body weight >130 kg

Exclusion criteria for the Lokomat therapy (affecting arm 1 - pusher):
• orthostatic circulatory disturbance
• unstable fractures or fractures sensitive to weightbearing
• severe osteoporosis
• skin problems in the area of the security cuffs
• known pre-existing joint problems (eg arthritis)
• significant asymmetries (eg discrepancy of leg length)
• Height below 160 cm and over 190 cm or a body weight >150 kg

Exclusion criteria for the GVS-stimulation (concerns arm 2 - neglect):
• metal implant(s) in the body
• brain tumor(s)
• inflammation of the scalp
• epilepsy
• degenerative or psychiatric disease(s)

Addresses

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- 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.*