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Randomised controlled trial of the effect of tilt table therapy with versus without an integrated stepping device on the level of consciousness of patients in persistent vegetative or minimally conscious state

Submission date 10/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/08/2006	**Overall study status** Completed	
Last Edited 24/06/2016	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Randomised controlled trial of the effect of tilt table therapy with versus without an integrated stepping device on the level of consciousness of patients in persistent vegetative or minimally conscious state

Study objectives
Tilt table therapy with an integrated stepping device is more effective in improving the level of consciousness than traditional tilt table therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Ethikkommission der bayerischen Landesärztekammer), 30/05/2006, registration number: 06018

Study design
Randomised single-blind controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Persistent vegetative or minimally conscious state

Interventions
Tilt table therapy with or without an integrated stepping device for three weeks

Intervention Type
Device

Phase
Not Specified

Primary outcome(s)
Level of consciousness measured by the Coma Recovery Scale - revised after three weeks of treatment and three weeks follow-up

Key secondary outcome(s))
1. Improvement in heart rate variability
2. To assess muscle tone/spasticity (modified Tardieu scale/Asworth scale)
3. To monitor reaction of blood pressure, heart rate and oxygen saturation during treatments
4. To assess Glasgow Outcome Score at discharge from hospital

Completion date

31/12/2008

Eligibility

Key inclusion criteria
1. In a persistent vegetative or minimally conscious state after traumatic brain injury, intracerebral hemorrhage or ischemic stroke, or in a minimally conscious state after hypoxia
2. Aged 18 to 70 years
3. Time since injury not more than six months
4. Not yet mobilised into standing for more than 30 minutes
5. Informed consent of legal proxy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Acute severe heart or lung disease (e.g. pneumonia, heart attack during the last four weeks)
2. Cardiac pace maker
3. Severe osteoporosis
4. Contractures or severe spasticity of lower extremities
5. Pregnancy
6. Unstable fractures or decubiti on lower extremities

Date of first enrolment
23/06/2006

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Germany

Study participating centre

Neurologische Klinik Bad Aibling
Bad Aibling
Germany
83043

Sponsor information

Organisation
Neurologische Klinik Bad Aibling (Germany)

ROR
https://ror.org/04fr6kc62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Neurologische Klinik Bad Aibling (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes