

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
Registration date 31/08/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/06/2016	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design

Interventional

Study design

Randomised single-blind controlled trial

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