

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/06/2016	Condition category Signs and Symptoms	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

Level of consciousness measured by the Coma Recovery Scale - revised after three weeks of treatment and three weeks follow-up

Secondary outcome measures

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

Overall study start date

23/06/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

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)

Sponsor details

Kolbermoorer Straße 72

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EKoenig@schoen-kliniken.de

Sponsor type

Hospital/treatment centre

Website

<http://www.schoen-kliniken.de>

ROR

<https://ror.org/04fr6kc62>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Neurologische Klinik Bad Aibling (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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