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Sympathetic effects of early mobilization in patients with severe brain injuries

Submission date
02/03/2016

Recruitment status
No longer recruiting

Registration date
08/03/2016

Overall study status
Completed

Last Edited
14/09/2016

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Severe brain injury is a blanket term used to describe brain injuries so severe that they require constant monitoring of their vital functions (heart rate, blood pressure, breathing and brain activity). This type of injury can be traumatic (an injury to the brain caused by a sudden blow to the head) or non-traumatic (which happens because of something happening inside the body, such as a stroke). One type of non-traumatic brain injury is a subarachnoid haemorrhage (SAH). This is an uncommon type of stroke in which a burst blood vessel causes sudden bleeding over the brain leading to increased pressure and oxygen starvation (cerebral ischaemia). There is a high risk of developing secondary complications of severe brain injury days after the event, including edema (swelling caused by a buildup of fluid) and vasospasm (where blood vessels are constricted, reducing blood flow). Bed rest is standard from people recovering from a severe brain injury so that their vital signs can be kept steady to reduce the risk of further complications. It has been shown however that prolonged bed rest can itself have a serious impact on health, affecting the muscles and bones, heart and blood vessels, skin, blood and even cognition (thinking ability). The aim of this study is to find out whether gradual, early mobilization (getting up and moving around) is a safe and effective way of rehabilitating patients who have experienced a severe brain injury.

Who can participate?
Adults with severe brain injury who have been in bed for at least a week and have been admitted to an Intermediate Care Unit.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are mobilized (moved) out of bed by physiotherapists using the usual techniques recommended at the hospital. Those in the second group are mobilized out of bed after receiving a session of MOTOmed-letto®. This is a machine which is secured to the end of the bed so that the patient can complete cycling exercises on foot pedals whilst lying down. Patients in the group use the MOTOmed-letto® for up to 30 minutes a day, five times a week. After a minimum of 7 days, these patients are mobilized out of bed immediately after a MOTOmed-letto® session. Those in the third group are mobilized out of bed according to the Erigo® method. The Erigo® is a tilting table with a build in leg movement system. This works by gradually moving the patient to an

upright position using patient leg movements. Participants in all groups have their blood pressure, heart rate and breathing rate measured when they are admitted to the Intermediate Care Unit, directly before first mobilization, during mobilization and one hour afterwards. The patients who are in hospital because of a SAH also have an ultrasound scan of their head to monitor their brain activity before and after mobilization. Participants in all groups also have a blood test before, during and after mobilization in order to measure chemicals showing how much stress the brain is under.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, although early mobilization could help reduce the risk of complications linked with prolonged bed rest. There is a risk that mobilization could increase brain stress and affect blood pressure, however patients will be closely monitored for their safety.

Where is the study run from?
University Hospital of Lausanne CHUV (Switzerland)

When is the study starting and how long is it expected to run for?
September 2011 to September 2015

Who is funding the study?
University Hospital of Lausanne CHUV (Switzerland)

Who is the main contact?
Dr Alda Rocca

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
Sympathetic activity and early mobilization in patients in intensive and intermediate care with severe brain injuries: a preliminary prospective randomized study

Study objectives
The aim of our study is to observe and quantify the changes in sympathetic activity with gradual postural changes (Erigo®) and with leg movements alone (MOTOmed®), after prolonged bed rest. Our hypothesis is that the gradual mobilization of neurologically impaired patients with these systems avoids orthostatic hypotension with a compensatory peak of catecholamines and thus is a safe method of early mobilization in patients with neurological deficits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission d'Ethique pour la Recherche sur l'être humain du canton de Vaud, 16/12/2011, ref: 341/11.

Study design
Single-centre prospective randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Brain injury

Interventions
Participants are randomized into 3 groups with different protocols of mobilization.

Group 1: Participants are mobilized out of bed by physiotherapists, according to usual clinical physiotherapy standard recommendations in the hospital.

Group 2: Participants are mobilized out of bed by physiotherapists for the first time after having received a session of MOTOmed-letto®. MOTOmed Letto® is an automatic system for leg mobilization in a supine position, miming a bicycle. Patients are mobilized in bed by either physiotherapists and with a MOTOmed® session of almost 30 minutes 5 days/week. Then, after a minimum of 7 days, patients are mobilized out of bed by physiotherapists for the first time after a MOTOmed® session.

Group 3: Participants are mobilized out of bed by physiotherapists for the first time following the Erigo® protocol. Erigo® is a tilting table with an integrated leg movement system, which allows progressive verticalization of the patient, adjustable to patient needs and possibilities. During the first step (5 minutes) the patient lies in a supine position, with their head at 0°, and the Erigo® started leg movements. During the second step (30 min) the patient is progressively verticalized (at 30°-50°-70° for 10 minutes each) while the Erigo® continues to move the patient's legs. During the third step (10 minutes) the patient is returned to a supine position.

Participants in all groups have their blood pressure, heart rate and respiratory rate measured at T1 (admission to the Intermediate Care Unit), T2 (the moment directly before the first mobilization out of bed), T3 (during the first mobilization out of bed) and T4 (one hour after lying in bed again). Participants also have a blood sample taken at T2, T3 and T4 to measure catecholamine and metanephrine concentrations, and those patients who have has a subarachnoid hemorrhage also have a transcranial Doppler at T1, T2 and T4.

Intervention Type
Behavioural

Primary outcome measure
Sympathetic activity is measured by detecting catecholamine (Epinephrine and Norepinephrine) and plasma free metanephrine (Metanephrine, Normetanephrine and Methoxytyramine) concentrations immediately before first mobilization out of bed, during the first mobilization out of bed and one hour after lying in bed again.

Secondary outcome measures
1. Blood pressure is measured using a sphygmomanometer upon admission to the Intermediate Care Unit, immediately before first mobilization out of bed, during the first mobilization out of bed and one hour after lying in bed again
2. Heart rate is measured using a heart rate montior upon admission to the Intermediate Care Unit, immediately before first mobilization out of bed, during the first mobilization out of bed and one hour after lying in bed again
3. Respiratory rate is measured using an optical breath rate sensor upon admission to the Intermediate Care Unit, immediately before first mobilization out of bed, during the first mobilization out of bed and one hour after lying in bed again
4. Cerebral blood flow velocity is measured using a transcranial Doppler (for patients with subarachnoid hemorrhage only) upon admission to the Intermediate Care Unit, immediately before first mobilization out of bed and one hour after lying in bed again

Overall study start date
12/09/2011

Completion date
02/09/2015

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Severe neurological injury - traumatic and non- traumatic injuries, requiring neurological, cardiovascular and respiratory functions monitoring 24/7 at the moment of the admission (for example subarachnoid hemorrhage, severe brain trauma, intra-parenchymal hemorrhage, ischemic vascular accident, brain anoxia)
3. Bed rest for at least 7 days
4. Continuous monitoring in the Intermediate Care Unit
5. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 patients divided into 3 groups of 10 patients

Key exclusion criteria
Exclusion criteria for Group 1:
Not meeting the inclusion criteria.

Exclusion criteria for Group 2:
1. Amputation of a leg, with impossibility to pedal
2. Trauma or previous surgery of the feet, pelvis or lumbar column
3. Abdominal open wound
4. Extreme obesity (BMI> 35)
5. Ulcers
6. Height <150cm
7. Psychiatric disease or severe agitation

Exclusion criteria for Group 3:
1. Fixed contractions of the legs
2. Weight >135 kg
3. Leg length <70 cm or > 102 cm
4. Bone instability

5. Open ulcers or vascular disease of the legs
6. Cardiac contro-indications
7. Inadequate cooperation of the patient

Date of first enrolment
27/07/2012

Date of final enrolment
02/09/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital of Lausanne CHUV
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Sponsor information

Organisation
Hocoma AG

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Sponsor type
Industry

ROR
https://ror.org/05becgp50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hocoma AG

Results and Publications

Publication and dissemination plan
Planned publication in the journal BMC Neurology.

Intention to publish date
30/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/09/2016		Yes	No