

# Sympathetic effects of early mobilization in patients with severe brain injuries

|  |  |   |
|--|--|---|
| <b>Submission date</b><br>02/03/2016   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>08/03/2016 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>14/09/2016       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> 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 built 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

**Contact name**

Dr Alda Rocca

**ORCID ID**

<http://orcid.org/0000-0001-9261-6969>

**Contact details**

University Hospital of Lausanne CHUV

Rue du Bugnon 46

Lausanne

Switzerland

1011

## 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 had 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 monitor 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**

Rue du Bugnon 46

Lausanne

Switzerland

1011

## **Sponsor information**

**Organisation**

Hocoma AG

**Sponsor details**

Industriestrasse 4

Volketswil

Switzerland

8604

+41 43 444 2200

info@hocoma.com

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 13/09/2016   |            | Yes            | No              |