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Hypothermia In Conscious Healthy Volunteers: a feasibility trial

Submission date	Recruitment status	[_] Prospectively registered
22/07/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
Animal and human studies suggest that mild hypothermia (low body temperature) has a beneficial effect for stroke and heart attack patients. The aim of this study is to investigate the feasibility and safety of using surface cooling to induce mild hypothermia (32-34°C) in healthy, conscious volunteers.

Who can participate?
Healthy volunteers aged 18 to 70

What does the study involve?
Surface cooling involves using a cooling pad to achieve a target temperature of 32-34°C for six hours. Shivering is prevented with drugs such as meperidine and buspirone and additional magnesium in eight of the participants. Core temperature is measured continuously with a temperature probe inserted through the nose into the esophagus (gullet). To avoid discomfort and vomiting a local anesthestic is applied. Comfort is assessed every 10 minutes during initial cooling, and every 30 minutes during maintenance cooling. Participants are monitored for shivering. In case of shivering or a low comfort score, more meperidine and meperidine are given to the participant. At the end of the observational period, the participants' skin is examined by a dermatologist.

What are the possible benefits and risks of participating?
There are no immediate benefits for the participants. When hypothermic treatment begins and the body temperature begins to drop, there will be mild increase in heart rate followed by a decrease in the heart rate as the temperature drops below 35.5°C, with a decrease in heart rate as temperature decreases further. Hypothermia weakens the immune functions and interferes with various inflammatory responses. Most studies using hypothermia for 24 hours or less have reported no or only small increases in infection rates. In initial studies with the device only minimal skin redness was observed, which resolved within minutes after removal of the blankets. No skin lesions were observed during the observation period. Platelet count and function and the body's mechanism to stop bleeding (coagulation) are impaired during hypothermia but bleeding problems are rare. No hypothermia study has reported significant problems with bleeding. The effect of meperidine on breathing and blood circulation is not

clinically significant in healthy volunteers. No relevant effects of buspirone on breathing and blood circulation have been observed.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
March to April 2011

Who is funding the study?
Emergency Medical Cooling Systems AG (Austria)

Who is the main contact?
Prof. Bernd Jilma

Contact information

Type(s)
Scientific

Contact name
Prof Bernd Jilma

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Additional identifiers

Protocol serial number
1.5

Study information

Scientific Title
Surface cooling for induction of mild Hypothermia In Conscious Healthy Volunteers: a feasibility trial

Acronym
HICHV

Study objectives
To investigate the feasibility and safety of non-invasive surface cooling for induction and maintenance of mild hypothermia (32-34°C) in healthy, conscious volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Vienna, 16/06/2009, Nr: 470/2009

Primary study design
Interventional

Study design
Prospective interventional cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke, acute myocardial infarction, cardiogenic shock

Interventions
Volunteers with an age of 18 to 70 years are included. After baseline measurements, meperidine (Alodan®, Gerot, Vienna, Austria) 1 mg/kg bolus, followed by 30 mg/h intravenously, and buspirone (Buspar®, Bristol-Myers Squibb, Meymac, France) 30 mg orally once will be given to prevent shivering. A single bolus of granisetron hydrochloride(Kytril®, Roche Austria, Vienna, Austria) 3 mg will be administered intravenously to prevent nausea. A continuous fluid drip with an isotonic electrolyte solution (Elomel iso®, Fresenius Kabi Austria, Graz, Austria) with an infusion rate of 100 ml/h will be administered throughout the cooling period. After eight subjects additionally a bolus of 4 g magnesium sulfate (MgSO4) over 30 minutes followed by a continuous intravenous drip of 2 g/h for 150 minutes will be given.

The cooling pads (EMCOOLSpad®, Emcools AG, Pfaffstaetten, Austria), each 20 x 30 cm, consists of multiple cooling cells filled with a patented cooling gel. The inner layer is a biocompatible film, that adheres to the patients skin on application and provides intimate pad to skin contact for efficient heat transfer. The cooling units are stored in a cooling box at -2°C before use. Six cooling units will be applied on back, thorax, abdomen, and thighs of the volunteers. The cooling units will be removed when a core temperature of 35°C is reached. Target core temperature will be 32-34°C and maintained for six hours.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Core temperature measured continuously with a temperature probe (Mon-a-therm® 9Fr/Ch; Tyco Healthcare, Mansfield, USA) advanced into the esophagus

Key secondary outcome(s)
1. Comfort score recorded every 10 minutes during initial cooling, and every 30 minutes during maintenance cooling
2. Shivering using a 4-point scale: 0 = no shivering evident; 1 = isolated facial or masticatory

fasciculation; 2 = peripheral shivering; 3 = uncontrolled rigor
3. Skin examination using a 5-points scale (severe - frost bites; moderate - skin trauma; medium - red skin; mild - pink skin; no visible skin irritation)

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Volunteers aged 18 to 70 years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Pregnant women
2. Subjects with a known pre-existing cardiopulmonary disease or pre-existing malignancy
3. A pre-existing coagulopathy
4. An active dermatologic condition
5. Current treatment with monamineoxidase inhibitors
6. Previous or current drug abuse
7. Known allergy to the study medication

Date of first enrolment
01/03/2011

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Wien
Austria
1090

Sponsor information

Organisation
Emergency Medical Cooling Systems (EMCOOL) AG (Austria)

Funder(s)

Funder type
Industry

Funder Name
EMCOOLS AG (Austria)

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	01/06/2011	23/10/2020	Yes	No