

Hypothermia In Conscious Healthy Volunteers: a feasibility trial

Submission date 22/07/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/10/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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 anesthetic 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

Contact details

Department of Clinical Pharmacology

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Austria

1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Prospective interventional cohort study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/03/2011

Completion date

30/04/2011

Eligibility**Key inclusion criteria**

Volunteers aged 18 to 70 years

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

16

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)

Sponsor details

Brucknerstrasse 6/7a

Wien

Austria

1040

Sponsor type

Industry

Website

<http://www.emcools.com>

Funder(s)

Funder type

Industry

Funder Name

EMCOOLS AG (Austria)

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