

# CONTROL OF HEAT STORAGE IN A COOL AND WARM ENVIRONMENT IN YOUNG AND ELDERLY MALES AND FEMALES

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In this study we test the hypothesis that a divisional calculation of heat loss, and incorporation of skin temperature of the extremities during mild cold exposure will indicate an age effect on heat loss between young and elderly males and females...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35511

### Source

ToetsingOnline

### Brief title

Heat storage, age and gender

### Condition

- Other condition

### Synonym

cooling and heating

### Health condition

aandoeningen bij thermoregulatie ten gevolge van voortgang in leeftijd

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** SenterNovem en ZonMw

## Intervention

**Keyword:** Age, Gender, Insulation, Temperature, Thermoregulation

## Outcome measures

### Primary outcome

Heat storage, Rate of change of heat storage

### Secondary outcome

-

## Study description

### Background summary

In general elderly are predisposed to risk of both hypothermia and hyperthermia, even at mild cold or heat exposure. Studies aimed at age related changes in mechanisms of thermoregulation to explain the increased risk of elderly failed to observe differences in heat loss between young and elderly. This might be caused by a lumped approach of calculation of heat loss through mean skin temperature without incorporation of temperatures of the extremities. Furthermore it is known that males and females differ in thermoregulation. Therefore, a second objective of this study is to explore gender effects in heat loss and heat storage.

### Study objective

In this study we test the hypothesis that a divisional calculation of heat loss, and incorporation of skin temperature of the extremities during mild cold exposure will indicate an age effect on heat loss between young and elderly males and females. An additional purpose is to test whether hysteresis effects are measurable between cooling and warming subjects

### Study design

Cross-over design covering both exposure to a mild cold and mild warm

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environment. Subjects will be studied on two separate occasions, where they are subjected to either a cold to warm or warm to cold temperature transition

### **Study burden and risks**

Subjects are required to visit the laboratory three times. The first visit is to select and match subjects based on body composition characteristics (duration 1 hour). The second and third visit concerns the actual experiment (duration 4 hours). Further than possible discomfort due to exposure to a mild cold and mild warm environment, no significant burden or risk for the subjects is expected. The capsule for core temperature measurement is designed for human use only. The capsule is easily swallowed and is not sensed during the rest of its tract through the body. The blood collection can cause a contusion.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

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## Inclusion criteria

- Caucasian healthy male or female
  - Age between 18 to 28 years or age between 68 to 78 years
  - $20 \text{ kg/m}^2 < \text{BMI} < 25 \text{ kg/m}^2$
  - $15\% < \text{Fat percentage} < 30\%$
  - $1.8 \text{ m}^2 < \text{Dubois skin area} < 2.0 \text{ m}^2$
  - $80\text{mmHg} < \text{Mean arterial pressure} < 90\text{mmHg}$  (rest, supine position)
- for females- using combination anti-conception or using no anti-conception

## Exclusion criteria

- History of cardiovascular disease
- Carrier of electrically-sensitive implanted devices
- Deviant core temperature at day of experiment
- General feeling of illness at day of experiment
- For females-the use of only estrogen or progesteron
- Smoking

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 04-01-2010

Enrollment: 60

Type: Actual

## Ethics review

Approved WMO

Date: 28-09-2009

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 17-03-2010

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register**

CCMO

**ID**

NL29167.068.09