

Human thermoregulatory behavior and thermo-physiology before and after mild heat acclimation in healthy lean and obese subjects

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1. To study thermoregulatory behavior and thermo-physiology of healthy lean and obese subjects before and after mild heat acclimation. 2. To define categories of *temperature preference* based on thermoregulatory behavior and thermo-physiology of...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40666

Source

ToetsingOnline

Brief title

Thermoregulatory behaviour and mild heat acclimation

Condition

- Other condition

Synonym

nvt

Health condition

geen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Agentschap NL;EOS LT project

Intervention

Keyword: Cardiovascular health, Mild heat acclimation, Thermoregulation, Thermoregulatory behavior

Outcome measures

Primary outcome

1. To study thermoregulatory behavior and thermo-physiology of healthy lean and obese subjects before and after mild heat acclimation.
2. To define categories of *temperature preference* based on thermoregulatory behavior and thermo-physiology of healthy lean and obese subjects.
3. To study the influence of mild heat acclimation on alertness and cardiovascular health of healthy lean and obese subjects.

Secondary outcome

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Study description

Background summary

Human beings are almost constantly exposed to indoor climates and in the last decades, overheating of buildings has become an important issue. In the western world, heating, ventilating and air-conditioning of residential, commercial and public buildings consumes a lot of energy. In developed countries, one-third of the primary energy supply is used for this purpose. This reveals the importance to reduce this energy use. A lot of progress has been made towards highly effective construction materials, which provide high standards of airtightness and insulation. However, as a result buildings might be at risk for

overheating. Furthermore, global warming is progressing slowly but surely. The indoor climate of a building has an important impact on human metabolism: uncomfortable warm environments might cause sleepiness and restrict productivity. On the other hand, building occupants influence their thermal environment to maximize their individual comfort: they open a window or put on a heater. Changes in skin and core temperature, as well as conscious perception of thermal sensation and thermal comfort, seem to drive thermoregulatory behaviour. It is difficult to predict how much energy a building will consume in practice, which might be due to the fact that the individuality of occupancy is not sufficiently implied in calculations. With respect to the issue of overheating, it is desirable to improve knowledge on how human thermoregulatory behaviour and thermophysiology can be influenced by heat acclimation, since evidence is very limited. It is hypothesized, that prolonged exposure to mild heat causes alterations in thermoregulatory physiology (as widely accepted), and influences behavioural set points of thermoregulation and shifts the perception of thermal comfort to higher ambient temperature.

Study objective

1. To study thermoregulatory behavior and thermo-physiology of healthy lean and obese subjects before and after mild heat acclimation.
2. To define categories of *temperature preference* based on thermoregulatory behavior and thermo-physiology of healthy lean and obese subjects.
3. To study the influence of mild heat acclimation on alertness and cardiovascular health of healthy lean and obese subjects.

Study design

The study will take place between March 2014 and December 2015. The measurements will be conducted at the Metabolic Research Unit (MRUM) of Maastricht University. The study will consist of 11 testing days at the laboratory (Figure 1). Day 1 will consist of a screening. During day 2 and 3, baseline measurements of the so-called SWITCH protocol (experimental protocol to measure thermoregulatory behavior) as well as protocol TNZwarm and TNZcold (thermo-neutral zone measurements) will take place. TNZwarmpre and SWITCHpre will be carried out at the same day (day 2) and TNZcoldpre at a separate day (day 3), followed by the first mild heat exposure. During the next 6 days, participants will visit the laboratory for an acclimation period that consists of 6.5h mild heat exposure per day. After completing day seven of the acclimation, participants will undergo protocol TNZwarm (TNZwarmpost), SWITCH (SWITCHpost) and TNZcold (TNZcoldpost) for a second time.

Intervention

Mild heat exposure. The volunteers will be exposed to a mild heat temperature (33°C) for 7 days. Day 1 consist of 4h mild heat exposure, followed by 6 days

of 6.5h mild heat exposure.

Study burden and risks

The risks of this study are low. The DEXA-scans, executed for the measurement of body composition is a non-invasive method. The radiation dose is very low, comparable to the radiation dose of a warm summer day or a radiation-photo taken at a dentists. The effective radiator dose is, depending on the duration of the scan (size of the body) between 1-7 microSievert (0,001- 0,007 mSv). We expect the subjects to sense superior thermal discomfort during the first few days of exposure, but this will gradually decline during the acclimation period. The temperatures will be uncomfortable in the first place but not harmful.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Caucasian healthy lean volunteers

- * Generally healthy
- * male or female
- * Age: 18 to 35 years
- * BMI: 20-25 kg/m²
- * Women using Microgynon 30 or levonorgestrel/ethinylestradiol; Inclusion criteria obese vrijwilligers
- * Generally healthy
- * male or female
- * Age 18 to 35 years
- * BMI 28-35 kg/m²
- * Women using Microgynon 30 or levonorgestrel/ethinylestradiol

Exclusion criteria

- * Participants that do not want to be informed about accidental medical findings, which might occur during the study.
- o If participants do not want us to inform their general practitioners about unexpected medical findings, they cannot participate in the study.;
- * Participate in physical activity more than 2x/week
- o We will exclude individuals that participate in endurance sports (like swimming, running, cycling) more than two hours per week. Endurance-trained athletes seem to have differing thermo-physiology, which has, amongst others, been recently confirmed by another study of our laboratory (Vosselman et al, submitted).
- * Participation in another biomedical study within 1 month before the first screening visit
- * Diabetes mellitus type I and II
- * Pregnancy
- * Unstable weight (weight gain or loss > 5 kg in the last three months)
- * Hypertension (systolic/diastolic blood pressure >140/90)
- * Hypotension (systolic/diastolic blood pressure <90/60)
- * General feeling of illness at day of experiment
- * (History of) cardiovascular diseases
- * Contraindications for the telemetric pill:
 - o In the presence of any known or suspected obstructive disease of the gastrointestinal tract, including but not limited to diverticulitis and inflammatory bowel disease
 - o A history of disorders or impairment of the gag reflex
 - o Previous gastrointestinal surgery
 - o Hypo motility disorders of the gastrointestinal tract including but not limited to Ileus

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 15-12-2014

Enrollment: 48

Type: Actual

Ethics review

Approved WMO

Date: 29-07-2014

Application type: First submission

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

Approved WMO

Date: 21-01-2015

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

ID: 20162

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL47779.068.14
Other	NRT, pending
OMON	NL-OMON20162

Study results

Date completed: 01-04-2016

Actual enrolment: 12

Summary results

Trial ended prematurely