Thermoregulatory behaviour and mild heat acclimation

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20162

Source
NTR

Brief title
TRB_ACCL

Health condition

human thermoregulation, thermoregulatory behaviour, thermophysiology, mild heat, mild heat acclimation, acclimation

Sponsors and support

Primary sponsor: Maastricht University Medical Center+
Source(s) of monetary or material Support: Agentschap NL, EOS LT project

Intervention

Outcome measures

Primary outcome

thermoregulatory behavior, thermal sensation, thermal comfort, thermo-physiological parameters (energy expenditure, core temperature, skin temperature, skin blood perfusion, local sweat rate, total sweat rate, skin conductance, shivering) and body composition

Secondary outcome

cardiovascular functions such as heart rate, blood pressure, hemodynamic parameters, blood parameters, gross motor activity and alertness

Study description

Study objective

1. There are differences of thermoregulatory behavior and thermo-physiology between healthy lean and obese subjects.

2. Healthy lean and obese individuals can be classified based on individual thermal preference, which is a result of distinct thermoregulatory behavior and thermo-physiology.

3. A seven-day mild heat acclimation affects thermal physiology, alertness and cardiovascular health of healthy lean and obese subjects.

Study design

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

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.

Contacts

Public
Universiteitssingel 50
H. Pallubinsky
Maastricht 6229 ER
The Netherlands
+31 43 384259
Scientific
Universiteitssingel 50
H. Pallubinsky
Maastricht 6229 ER
The Netherlands
+31 43 384259

Eligibility criteria

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/ehinylestradiol

Inclusion criteria obese volunteers

• 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 Illeus

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	48
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40666
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4388
NTR-old	NTR4519
CCMO	NL47779.068.14
OMON	NL-OMON40666

Study results