Thermoregulatory behavior.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20014

Source
NTR

Health condition

Thermal behavior, thermal comfort, thermal sensation, physiology

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)
Source(s) of monetary or material Support: Agentschap NL

Intervention

Outcome measures

Primary outcome

1. The intention of thermoregulatory behavior, using a questionnaire;

2. Energy expenditure, as measured using indirect calorimetry in a climate controlled respiration chamber.

Secondary outcome

1. Thermal comfort, using a questionnaire with a VAS;

2. Thermal sensation, using a questionnaire with a VAS;

3. Thermal environment, using a questionnaire with a VAS;

4. Skin temperature, using iButtons;

5. Core temperature, using an ingestible pill;

6. Skin perfusion, using Laser Doppler Flowmetry;

7. Blood parameters.

Study description

Background summary

The volunteers will be measured at home and in an experimental setting where they will be exposed to heat and cold during three different trails. This will be done in order to study the effect of physiological parameters on thermoregulatory behavior, and on thermal comfort and sensation.

Study objective

The intention to change behavior is related to changes in multiple physiological variables. Thermal comfort and thermal sensation are related to these physiological parameters. Furthermore, the intention of behavior is related to changes in thermal comfort and thermal sensation.

Study design

Participants will be instructed for a 24-hour measurement at home (1 hour) and will visit the research facility three times for 3.5 hour.

Intervention

Cold and heat exposure during three trials:

1. Protocol A is composed of a neutral-to-warm transition in ambient temperature (24°C to 32°C, with 4 K/h);

2. Protocol B is composed of a neutral-to-cold transition in ambient temperature (24°C to 16°C, with 4 K/h);

3. During protocol C ambient temperature will be varied between three fixed temperatures (16°C, 24°C and 32°C).

Contacts

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Eligibility criteria

Inclusion criteria

1. Caucasian healthy females on oral contraceptive;

2. Age: 18 to 30 years;

3. BMI: 20-25;

4. Fat percentage: 20-30%.

Exclusion criteria

1. Regular medication use;

2. Pregnancy;

3. Hypertension (systolic/diastolic blood pressure >140/90);

4. Hypotension (systolic/diastolic blood pressure <90/60);

5. General feeling of illness at day of experiment;

6. (History of) cardiovascular diseases;

7. In the presence of any known or suspected obstructive disease of the gastrointestinal tract, including but not
limited to diverticulitis and inflammatory bowel disease;

8. A history of disorders or impairement of the gag reflex;

9. Previous gastrointestinal surgery;

10. Hypo motility disorders of the gastrointestinal tract including but not limited to Illeus.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2012
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion

Date:	12-07-2012
Application type:	First submission

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	ID
NTR-new	NL3376
NTR-old	NTR3524
Other	METC / CCMO : 11-3-065 / NL38216.068.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A