The effect of mild heat acclimation on insulin sensitivity and thermophysiology

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Primary objective:o To evaluate the effect of mild heat acclimation on insulin sensitivity in obese men and womenSecondary objectives:o To evaluate the effect of mild heat acclimation on insulin signalling and heat shock protein expression in human...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON43282

Source
ToetsingOnline

Brief title
Mild heat and insulin sensitivity

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
impaired fasting glucose/impaired glucose tolerance, Insulin sensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Insulin sensitivity, Mild heat acclimation, Prediabetes, Thermophysiology

Outcome measures

Primary outcome

Main study parameter/endpoint

o Insulin sensitivity

Secondary outcome

Secondary study parameters/endpoints

o Insulin signalling and heat shock protein expression in human muscle

o Energy expenditure

o Total sweat loss and sweat rate

o Core body temperature, skin temperature distribution and skin blood flow

o Cardiovascular parameters (blood pressure, heart rate and cardiac output)

o Subjective perception of the thermal environment

Other study parameters (if applicable)

o Body composition (DEXA)

o Glucose tolerance (OGTT)

Study description

Background summary

Recent studies evidenced the positive effect of heat treatment on insulin resistance in rodents. Heat treatment, more specifically hot water immersion of the lower body, improved insulin signalling and increased heat shock protein 72 expression in diabetic rodent muscle tissue. Heat shock protein expression

positively correlates with increased glucose metabolism and is therefore anticipated to participate in insulin signalling mechanisms. However, human data is very limited. We have recently shown that relatively mild passive heat acclimation in young healthy subjects evokes in part similar physiological adaptations as accomplished by more intense combined heat acclimation and exercise studies. For instance, mild heat acclimation induced a decrease in core temperature and evoked an earlier increase of energy expenditure upon exposure to warm temperatures.
We therefore hypothesize, that in obese subject with high risk for the development of pre-diabetes (impaired fasting glucose, IFG and/or impaired glucose tolerance, IGT) or diabetes, passive mild heat acclimation (35*C) will improve insulin signalling, which might improve insulin resistance and thereby reduce the risk for the development of the respective symptoms and diseases.

Study objective

Primary objective:
o To evaluate the effect of mild heat acclimation on insulin sensitivity in obese men and women

Secondary objectives:
o To evaluate the effect of mild heat acclimation on insulin signalling and heat shock protein expression in human muscle tissue of obese men and women
o To evaluate the effect of mild heat acclimation on energy expenditure during heat exposure in obese men and women
o To evaluate the effect of mild heat acclimation on total sweat loss and sweat rate during heat exposure in obese men and women
o To evaluate the effect of mild heat acclimation on core temperature, skin temperature distribution and skin blood flow during heat exposure in obese men and women
o To evaluate the effect of mild heat acclimation on cardiovascular parameters during heat exposure inobese men and women
o To evaluate the effect of mild heat acclimation on subjective perception of the thermal environment during heat exposure in obese men and women

Study design

The study will be carried out in a pre-test/post-test design. 13 obese men and women (BMI between 25-35kg/m2) will be included after being screened for in- and exclusion criteria. If eligibility is assessed, volunteers will be invited to participate for 12 consecutive study days, whereof 4 measurement days (2 full measurement days (1 and 12, each 8h) and 2 half measurement days (2 and 11, each 3.5h)) and 10 days of mild heat acclimation (8 full (6h) and 2 half acclimation days (4h)).

Intervention

The intervention consists of 10 days (2 half days (4h) and 8 full days (6h)) of passive mild heat acclimation to 35*C.

Study burden and risks

Although complications are rare, each measurement involves some risks. During hyperinsulinemic euglycemic clamp subjects might exhibit symptoms of hypoglycaemia. Muscle biopsies might be complicated by bleeding, infection or nerve damage. After the local anaesthetics wear off, subjects might exhibit pain. The intravenous cannula used during the clamp may cause a haematoma. The effective dose of the DXA-scan is 1-7 microSievert and this is considered as a low risk.There are no personal benefits associated with participation, but participation can help to gain more knowledge about the effects of heat acclimation on insulin sensitivity in prediabetic persons. The intervention may affect or improve the glucose metabolism, but this is not certain. The investigators will provide the participants with their study results after the study is finished, if they wish so.

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

o Men and women
o Caucasian race
o Age 40-70 years
o BMI between 25 and 35 kg/m2
o Steady dietary habits
o Generally healthy, no medication use that interferes with metabolism. If volunteers need medication (e.g. statin drugs, NSAIDs), it will be reviewed with the dependent physician on individual basis.
o Women after their menopause, meaning no menstrual cycle for at least 24 months and only if they are not under hormonal treatment.

Exclusion criteria

o Haemoglobin <8.4mmol/L
o No signs of active uncontrolled hypertension, liver of kidney malfunction
o Cardiac problems and cardiovascular diseases, such as angina pectoris, cardiac infarction and arrhythmias
o Any medical condition requiring treatment and/or medication that interferes with investigated parameters. Medical conditions and treatments will be discussed with the dependent physician on individual basis
o Anticoagulation medication
o Unstable body weight (weight gain or loss >3kg in the past three months)
o Participation in another biomedical study within 1 month prior to screening visit
o Volunteers, who do not want to be informed about unexpected medical findings, or do not wish that their treating physician will be informed, cannot participate in this study
o Blood donation three month prior to study and three month after finishing study
o Women will be excluded if their last menstrual cyclus was less than 24 months ago and if they are under hormonal treatment (to alleviate symptoms of the menopause).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2017
Enrollment:	43
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-10-2016
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: 27050

Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56876.068.16
OMON	NL-OMON27050