The effect of cold exposure on the glycaemic and insulinaemic responses to an oral glucose load

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Primary objectives: 1) To investigate the effect of cold exposure on the glycaemic and insulinaemic responses to an oral glucose load in healthy male adults. 2) To investigate the effect of cold exposure on the glycaemic and insulinaemic responses...

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

Summary

ID

NL-OMON45781

Source
ToetsingOnline

Brief title
The effect of cold exposure on glucose tolerance

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
High blood sugar. Hyperglycaemia.

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cold exposure, Glucose tolerance, Hyperglycaemia, Shivering

Outcome measures

Primary outcome

The primary research parameters are the changes in glucose and insulin concentrations after the oral glucose tolerance test.

Secondary outcome

Exploratory parameters:

Energy expenditure (using indirect calorimetry)

Shivering activity (using surface electromyography)

Core (using a telemetric pill) and skin temperatures (using iButtons)

Skin blood flow (using laser doppler flowmetry)

Thermal sensation and comfort (using questionnaires)

Blood pressure and heart rate (using automatic blood pressure cuff and a heart rate band)

Plasma glucose, lactate, adrenaline and noradrenaline in response to cold exposure

Plasma volume changes (using haematocrit and haemoglobin values)

Study description

Background summary

The purpose of the study is to evaluate the effect of cold exposure on an individual's glucose tolerance. Previous research has already shown that 10 days acclimation to a mild cold environment (14-15°C) can enhance insulin sensitivity. However, the duration in the cold environment was 6 hours per day

which may not be practical for everyone. Therefore, the present study will investigate the effect of a shorter, and more intense cold exposure on an individual's glucose tolerance. It is hypothesised that cold exposure before consuming a glucose drink will enhance glucose clearance.

Study objective

Primary objectives:
1) To investigate the effect of cold exposure on the glycaemic and insulinaemic responses to an oral glucose load in healthy male adults.
2) To investigate the effect of cold exposure on the glycaemic and insulinaemic responses to an oral glucose load in adults with prediabetes.

Exploratory Objective(s):
To investigate the effect of cold exposure on additional parameters linked to energy metabolism and thermoregulation.

Study design

Sixteen healthy adult males will be recruited for a cross-over design study, consisting of one screening, two test days and two short visits before the test days. The participants will be exposed to two thermal conditions on two test days. The first test day will always be cold exposure and then the second test day will be exposure to a thermoneutral temperature (serving as the control). The temperature intervention will be followed by a 1.5 h rest and then an oral glucose tolerance test (OGTT). Immediately before and 3 h following the intake of the glucose drink, blood sampling will be performed to monitor glucose and insulin concentrations. Between each test day there will be at least 10 days to prevent the previous test effecting the next test.
Depending on the outcome of the study in healthy adult males, the study may be repeated with 16 adults with prediabetes as the target population. If the cold exposure is accepted by the healthy population it would be important to then test the cold exposure in a population with disturbed glucose metabolism, with the aim to investigate if the cold exposure can improve hyperglycaemia.

Intervention

Participants will be wrapped in a water-perfused suit. The temperature of the suit will be lowered to 10°C. From the onset of shivering, the participants will remain in the suit for 1 hour.

For the control:
Participants will be wrapped in a water-perfused suit. The temperature of the suit will remain at a thermoneutral temperature (32°C) to avoid shivering and excessive sweating. The duration will be matched to that of the cold exposure.

Study burden and risks

In this study, the major burdens are the frequent blood drawings and the cold exposure. The frequent blood drawings may cause a haematoma after venapuncture. Even a small puncture when blood is drawn may cause pain or discomfort. Other risks are swelling of the vein and bleeding or bruising at the site of entry of the skin. With the use of sterile techniques by trained personnel, these risks are minimalised.
The frequent blood drawings can potentially be dangerous in the case of anaemia. Therefore, subjects with a low haemoglobin content will be excluded during screening. Additionally, an unexpected medical finding can potentially be detected and participants may feel nauseous after consuming the glucose drink.

The cold exposure may be perceived as uncomfortable by the participants. However, this should not inhibit the research from taking place as exercise may also be perceived as uncomfortable, yet the benefits to health are evident. This study will provide insight into the effect of a more practical, individualised cold exposure on glucose tolerance. Although further research would be required, the research may lead to a new therapeutic option for the treatment of type 2 diabetes.

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

Inclusion Criteria of healthy population (n<=16):;Signed informed consent.
White European.
Male.
Age 18 - 40 years at the start of the study.
BMI * 20 and < 30 kg/m2.;Inclusion criteria of impaired glucose metabolism population (n<=16):;Signed informed consent.
White European.
Male or female.
Women should be postmenopausal or use hormonal contraconceptives.
Age 30 * 75 years at the start of the study.
BMI * 25 and <35 kg/m2.
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 an individual basis.
Impaired fasting glucose (5.6 mM to 6.9 mM) and/or blood glucose values 7.8-11.0 mM 2h after glucose drink consumption during OGTT in screening, based on the criteria set by the American Diabetes Association.

Exclusion criteria

Healthy population exclusion criteria:;Smoking.
Active diseases (cardiovascular, diabetes mellitus, liver, kidney, cancer or *other).
Cold-acclimated, such as takes daily cold showers or baths, or works in a refrigerated environment, or visit of a place with cold climate (e.g. skiing holiday), within 1 month previous to the start of the study.
Unstable body weight (gain or loss > 5kg in last 3 months).
Currently undertaking a diet.
Hb <8.4 mmol/L.
Performs strenuous exercise on most days of the week.;Impaired glucose metabolism population exclusion criteria:;Smoking.
Active diseases (cardiovascular, diabetes mellitus, liver, kidney, cancer or *other).
Cold-acclimated, such as takes daily cold showers or baths, or works in a refrigerated environment, or visit of a place with cold climate (e.g. skiing holiday), within 1 month previous to the start of the study.
Unstable body weight (gain or loss > 5kg in last 3 months).

Currently undertaking a diet.
Men: Hb <8.4 mmol/L, Women: Hb <7.8 mmol/L. *
Performs strenuous exercise on most days of the week.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2019
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	14-11-2018
Application type:	First submission
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	ID
ClinicalTrials.gov	NCT03700164
CCMO	NL67500.068.18