The long-term effect of 10 days cold in diabetic patients.

No registrations found.

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

Summary

ID

NL-OMON22285

Source
NTR

Health condition

Cold acclimation
Non insulin depended diabetes mellitus
Insulin sensitivity
Obesitas (BMI 28-35)
Cardiovascular risks
Lipid metabolism
Insulinegevoeligheid
Koude acclimatie
Overgewicht
Diabetes mellitus type 2
Vetmetabolisme
cardiovasculair risico

Sponsors and support

Primary sponsor: Maastricht university (NUTRIM)
Source(s) of monetary or material Support: CVON (Hartstichting Nederland)

Intervention

Outcome measures

Primary outcome

- Insulin sensitivity as determined by hyperinsulinemic euglycemic clamp.

- Metabolism of triglyceride, cholesterol and lipoproteins after a meal.

Secondary outcome

- Endothelial dependent and independent vasodilation (measured with Laser Doppler Flowmetry and iontophoresis)

- Arterial stiffness (measured with Pulse Wave Velocity)

- Central retinal arterial equivalent (CRAE), central retinal vein equivalent (CRVE) and arteriovenous ratio (AVR)

- Muscle biopsy: analysis of insulin signalling and insulin independent pathway causing GLUT4 translocation. Analysis of other relevant markers of energy metabolism. Cell culture to investigate the underlying molecular pathway. Skeletal muscle lipid accumulation (measured by immunofluorescence microscopy).

- Intrahepatic lipid content (measured with 1H-MRS)

- Skin temperature during cold exposure

- HbA1c, endothelial/inflammatory markers and energy metabolism markers

- Thermal sensation and comfort

Study description

Background summary

Type 2 diabetes is a major health problem and is accompanied with increased cardiovascular disease risk. Cold exposure has received much attention over the past years as a potential strategy to improve metabolic health. It has previously been shown that 10 days of cold acclimation markedly improved skeletal muscle insulin sensitivity in patients with type 2 diabetes. However, whether cold acclimation also affects postprandial metabolism and cardiovascular risk markers remains unknown. We aimed to investigate whether cold acclimation beneficially affected postprandial metabolism and cardiovascular risk markers, and if the effect on insulin sensitivity was sustained for a longer period of time.

Study objective

The beneficial effect of cold acclimation on insulin sensitivity is reproducible and the effect wil sustain for a longer period of time. Besides insulin sensitivity, cold acclimation also has beneficial effects on cardiovascular risk factors in type 2 diabetes.

Study design

- Insulin sensitivity: day 4, 19 and 29

- Lipid metabolism: day 1 and 16

- Endothelial and vascular function: day 1 and 16

- Muscle biopsy: day 4, 19 and 29

- Intrahepatic lipid content: day 4 and 19

- Skin temperature: day 6, 8 and 15

- Thermal sensation and comfort: day 6-15

- Endothelial/inflammatory markers; energy metabolism markers: day 1 and 16; day 4 and 19

- Mean glycosylated hemoglobin A1C: day 83

Intervention

Cold acclimation by staying ten days in a climate chamber of 16 °C

Contacts

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Eligibility criteria

Inclusion criteria

- Caucasians

- Age: 45 – 70 years

- BMI: 28-35 kg/m2

- Gender: male or female

- Women should be postmenopausal

- Diagnosed with type 2 diabetes at least 1.5 years before the start of the study

- Relatively well-controlled type 2 diabetes: HbA1c < 8.5%

- Oral glucose lowering medication (metformin only or in combination with sulfonylurea agents)

- No signs of active diabetes-related co-morbidities like active cardiovascular diseases, active diabetic foot, polyneuropathy or retinopathy.

- No signs of active liver or kidney malfunction.

Exclusion criteria

- Participate in physical activity more than 2x/week

- Unstable body weight (weight gain or loss > 5 kg in the last three months)

- Participation in another biomedical study concerning brown adipose tissue within 1 month before the first screening visit

- Insulin dependent type 2 diabetes patients

- Smoking

- Men: Hb <8.4 mmol/L, Women: Hb <7.8 mmol/l

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2016
Enrollment:	16
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-02-2016
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	NL4469
NTR-old	NTR5711
Other	MEC : 153030

Study results