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

Gepubliceerd: 02-02-2016 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22285

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht university (NUTRIM)
Overige ondersteuning: CVON (Hartstichting Nederland)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Insulin sensitivity as determined by hyperinsulinemic euglycemic clamp.
- Metabolism of triglyceride, cholesterol and lipoproteins after a meal.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-02-2016
Aantal proefpersonen:	16
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	02-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4469
NTR-old	NTR5711
Ander register	MEC : 153030

Resultaten