Does the lowering in fat mobilisation during exercise lead to greater improvements in glycemic control in type 2 diabetes?

Gepubliceerd: 30-07-2014 Laatst bijgewerkt: 18-08-2022

Lipolysis inhibition during endurance exercise leads to a significantly greater improvement in 24-hour glycemic control in type 2 diabetes, as opposed to endurance exercise under normal circumstances.

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

Samenvatting

ID

NL-OMON22784

Bron
Nationaal Trial Register

Verkorte titel
LIDE

Aandoening

Type 2 diabetes

Ondersteuning

Primaire sponsor: Universiteit Maastricht Medical Centre
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

24-hour glycemic control: serial measurements of blood glucose, insulin levels, and calculation of HOMA-IR index.

Toelichting onderzoek

Doel van het onderzoek

Lipolysis inhibition during endurance exercise leads to a significantly greater improvement in 24-hour glycemic control in type 2 diabetes, as opposed to endurance exercise under normal circumstances.

Onderzoeksopzet

During 24 hours, 23 blood samples will be collected.

Onderzoeksproduct en/of interventie

Subjects are randomly assigned, by envelope, to an acute exercise bout with acipimox administration, followed one week later by an acute exercise bout with placebo intake, followed one week later by a control situation (no exercise) and placebo intake, or to the opposite follow order (=three experimental visits/subject). At entry of study following measurements will be executed (screening): fasting blood sample for assessment of glycemic control and lipid profile, oral glucose tolerance test, maximal cardiopulmonary exercise test, and body composition assessment. Oral blood-glucose and/or lipid-lowering medication intake remains constant during the study. During the three experimental visits, food intake will be standardized and serial blood samples will be taken.

All participants perform an acute endurance exercise bout on bike, for a total duration of 60 min, at exactly 45% of baseline peak cycling power output. The exercise intensity is monitored by continuous heart rate monitoring (Polar, Oy, Finland). Ahead of exercise, and immediately after exercise, blood pressure is assessed manually.

In one experimental trial, subjects are orally administered one capsule of 250mg acipimox (Nedios, Altana Pharma bv, Hoofddorp, NL). Potential side-effects of acipimox intake are: flushing, skin rashes, gastrointestinal complaints, headaches. In the other experimental trials, subjects are administered one capsule of 250mg of placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Twelve male T2DM patients (fasting blood glucose level >125mg/dl, and/or HbA1c >6.5%) will be included. Subjects with following characteristics will be included: age 45-70 years, body mass index 27.5-35.0 kg/m², sedentary (<2 hours sport/week), treated by oral blood glucose lowering medication, no exogenous insulin therapy, no history of coronary events/revascularization, absence of chronic pulmonary, renal disease, gastric complaints/disease, and/or orthopedic disease that interferes with exercise, no involvement in exercise training and/or caloric restriction program for at least one year.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exogenous insulin therapy, history of coronary events/revascularization, presence of chronic pulmonary, renal disease, gastric complaints/disease, and/or orthopedic disease that interferes with exercise, involvement in exercise training and/or caloric restriction program for at least one year

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2014
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-07-2014
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	NL4354
NTR-old	NTR4710
Ander register	: LIDE2104-1

Resultaten

Samenvatting resultaten
none