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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22784

Source
Nationaal Trial Register

Brief title
LIDE

Health condition

Type 2 diabetes

Sponsors and support

Primary sponsor: Universiteit Maastricht Medical Centre
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

24-hour glycemic control: serial measurements of blood glucose, insulin levels, and

calculation of HOMA-IR index.

Secondary outcome

Blood free fatty acid, triglyceride, and lactate levels.

Study description

Study objective

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.

Study design

During 24 hours, 23 blood samples will be collected.

Intervention

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.

Contacts

Public
Maastricht University
D. Hansen
Maastricht
The Netherlands
Scientific
Maastricht University
D. Hansen
Maastricht
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2014
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-07-2014
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	NL4354
NTR-old	NTR4710
Other	: LIDE2104-1

Study results

Summary results
none