Het effect van een suikerbelasting op de vaatwand van de aorta.

No registrations found.

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

Summary

ID

NL-OMON24498

Source
Nationaal Trial Register

Health condition

Diabetes mellitus 2 (ouderdomssuikerziekte)
Aortic elasticity (flexibiliteit van de aorta)

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: CTMM

Intervention

Outcome measures

Primary outcome

1. Magnetic resonance imaging: Aortic pulse wave velocity;

2. Heart rate variability.

Secondary outcome

1. Heart dimensions: End-diastolic volume, end systolic volume, LV mass, LV mass index,

LVMI/EDVI;

2. Heart function: Systolic function (stroke volume, ejection fraction, cardiac output, cardiac index, peak ejection rate), diastolic function (early peak filling rate E, early deceleration peak, atrial peak filling rate A, E/A ratio, peak mitral annulus longitudinal motion, MR estimate of LV filling pressure);

3. Body fat distribution;

4. Glucose and insulin levels.

Study description

Background summary

Study of the effects of postprandial hyperglycemia in patients with impaired fasting glucose versus matched controls on aortic elasticity measured by the pulse wave velocity and heart rate variability.

Study objective

Postprandial hyperglycemia has a negative effect on aortic elasticity in patients with impaired fasting glucose versus matched controls.

Study design

2 study days separated by 7-day intervals.

Each study day will consist of approximately 5 hours. For the study protocol the total examination time will be 80 minutes for the first MRI scan and 60 for the second MRI scan.

Intervention

Subjects will arrive after an overnight fast. A cannula will be inserted for blood drawing during the MRI scan. MRI scan will be performed to measure baseline cardiac function, abdominal waist fat and pulse wave velocity. After this MRI scan heart rate variability will be measured by a 5 minurte ECG registration. Subsequently the patient will drink on one study day a 75g oral carbohydrate load (75g dextrose in 300 ml water) and on the other study day only 300 ml water as contol. At 30, 60, 90 and 120 minutes post-carbohydrate load, blood samples will be collected for insulin and glucose levels. Post-carbohydrate MRI evaluation of pulse wave velocity is performed at one or two hours after the carbohydrate load. Heart rate variability will me measured again immediately after the MRI scans. Optimal time of measurement will be defined in six patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Impaired fasting glucose (fasting glucose 5.6-6.9 mmol/l);

2. Age 18-75 years;

3. Informed consent.

Controls:

1. Subjects with normal fasting glucose matched for age (18-75), BMI, blood pressure and gender;

2. Informed consent.

Exclusion criteria

1. Fasting plasma glucose =/. 7 mmol/l or previously diagnosed T2DM;

2. Grade 2 or 3 hypertension at screening according to ESC guidelines 2007;

3. Use of medication; antihypertensives, glucose lowering medication, statins of fibrates;

4. Any significant chronic disease;

5. Renal, hepatic or other endocrine disease;

6. Smoking;

7. Pregnancy;

8. Contra-indications MRI;

9. Recent participation in other research projects in one year.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-03-2010
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-07-2010
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	NL2320
NTR-old	NTR2426
Other	MEC LUMC : P09.241
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A