Effect of transient high blood glucose on brachial artery function

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To study the effect of transient high blood glucose level on the brachial artery FMD response, and to determine the reproducibility of the measurements and observed effect.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational invasive

Summary

ID

NL-OMON34359

Source
ToetsingOnline

Brief title
Effect of transient high blood glucose on brachial artery function

Condition

- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular disease, endothelial dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endothelial function, Flow-mediated dilation, Glucose, Insulin

Outcome measures

Primary outcome

FMD, local brachial artery pressure and cyclic change in diameter (distension)

as a function of blood glucose en insulin concentrations.

Secondary outcome

Correlations of selected biomarkers of endothelial function with mentioned

primary study parameters. Also changes therein as a function of blood glucose

en insulin concentrations.

Study description

Background summary

Cardiovascular complications play an important role in diabetes mellitus. These problems are mainly caused by vascular dysfunction. Normally, an artery dilates in response to an increased blood flow through it, which is known as flow-mediated dilation (FMD). FMD is blunted or absent in people with diabetes. However, it is not yet clear how exactly an elevated blood glucose level causes vascular dysfunction. In healthy volunteers, it remains to be investigated what the effect of a transiently increased blood glucose level is on the FMD response. This is partly due to the fact that measuring FMD is technically challenging. Recently, sensitive methods have become available to assess brachial artery FMD non-invasively. Accurate measurement of the effect of a high blood glucose level on FMD may contribute to improved diagnosis of vascular dysfunction in diabetic and obese patients. In this study, blood biomarkers of endothelial function are also taken into account to determine possible correlations between those biomarkers and FMD, as function of blood glucose.

Study objective

To study the effect of transient high blood glucose level on the brachial artery FMD response, and to determine the reproducibility of the measurements

and observed effect.

Study design

In 30 healthy volunteers multiple FMD measurements are performed: 2 times under baseline conditions, plus 30 and 75 minutes after intake of a standardized glucose-solution. Herewith, we are able to determine whether or not and what kind of effect an elevated blood glucose level (i.e. via insulin) has on brachial artery reactivity over time. This entire measurement session is repeated after about one week to see whether effects are reproducible.

Study burden and risks

Time investment is considerable, given the repeated session a week later (2 times 3 hours, within 1-2 weeks). Measurements are non-invasive, apart from blood sampling and oral glucose tolerance test (OGTT). The latter two are routinely used clinically. Complications and risks thereof can be managed reasonably well by planned procedures and precautions: A. There is a small risk of bleeding and infections with/after blood sampling, which are minimized by applied pressure on the wound and sterile materials and needle insertion and removal. B. After measurements, hypoglycemia (blood glucose dipping) might occur. Study subjects are therefore prompted to eat something after measurements. Psychological stress is anticipatedly minor, considering previous experience in volunteers and patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

male, aged 18+, fasting glucose below 6.1 mmol/l (point-of-care blood test, see E.6, item 2.)

Exclusion criteria

Female
Non-compliance with one of the following fasting requirements 12 hours prior to measurement:
* Medication
* Smoking
* Caffeine
* Vitamin supplements
* Exercise
* Food and drinks (only water permitted till 3 hours prior to measurements)
Fasting blood glucose level higher than 6.1 mmol/l (point-of-care meter; capillary blood sample).

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-10-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL33485.068.10