Cognitive performance in relation to glucose tolerance

Published: 09-06-2010
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To investigate cognitive performance in relation to glucose tolerance in elderly subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34345

Source
ToetsingOnline

Brief title
Cognitive performance and glucose tolerance

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
glucose sensitivity, insulin resistance

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: Cognition, Diabetes, Glucose tolerance, Memory

Outcome measures

Primary outcome

1. Assessment of peripheral glucose regulation by means of the standard 2-h

oral glucose tolerance test (OGTT)

2. Assessment of cognitive performance by means of a computerized validated

test system.

Secondary outcome

not applicable

Study description

Background summary

A strong association exists between abnormalities in glucose tolerance and adverse health outcomes, such as development of type 2 diabetes and cardiovascular disease. Several lines of evidence suggest that abnormalities in glucose tolerance are also associated with impaired cognitive performance. Previous studies have also shown that glucose administration enhances cognitive performance in healthy subjects and in subjects with memory deficits or poor glucose regulation.
In this study, a number of selected validated cognitive tests will be used to:
1) evaluate the association between cognitive performance and blood glucose regulation in a random sample of the elderly population. Cognitive tests are selected that target the cognitive domains being most sensitive to the effects of glucose tolerance, i.e. memory, vigilance, and attention;
2) evaluate the effect of glucose when considering the relationship between glucose tolerance and cognition, or in other words, to evaluate whether worse glucoregulators receive a greater cognitive benefit from glucose consumption than better glucoregulators.

Study objective

To investigate cognitive performance in relation to glucose tolerance in elderly subjects.

Study design

An open study. All subjects visit the institute once for OGTT and cognition tests.

Intervention

The intervention is part of the oral glucose tolerance test (OGTT) and consists of single administration of 75 g glucose dissolved in 300 ml water.

Study burden and risks

The burden of participation involves: filling in a questionnaire on health and lifestyle for screening, fasting from 22:00 h the evening before the test day, consumption of a glucose solution, no eating, drinking, smoking during the OGTT, possibly nausea and faintness due to the glucose solution, 2x blood sampling (ca. 17 ml), 2x conducting cognition tests on a computer. Participation is not likely associated with any physical and physiological discomfort.

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

1. Healthy as assessed by the TNO health and lifestyle questionnaire (short version)
2. Age 65-75 y (boundaries included) at Day 01 of the study
3. Able to perform easy actions on a computer
4. Voluntary participation
5. Having given written informed consent
6. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years
7. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

1. Having (a history of) medical or surgical events that may significantly affect the study outcome, including psychiatric disorders, diabetes
2. Use of medication for diabetes
3. Alcohol consumption > 28 units/week for males and > 21 units/week for females
4. Personnel of TNO Quality of Life, their partner and their first and second degree relatives
5. Not having a general practitioner
6. Not willing to accept information-transfer regarding his/her health, like laboratory results, findings at anamnesis and eventual adverse events to and from his general practitioner.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	09-06-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL32593.028.10