The effects of dopamine depletion on endogenous glucose production in healthy subjects

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We would like to eludicate the role of dopamine on glucose metabolism.

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

Summary

ID

NL-OMON33972

Source
ToetsingOnline

Brief title
AMPT-CLAMP

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dopamine, Insuline, Resistance, UHR

Outcome measures

Primary outcome

Glucose productions (suppression)

Secondary outcome

n.a.

Study description

Background summary

(page 2-4 vof the protocol)
It has been hypothesized that dopamine (DA) may be involved in the modulation of glucose metabolism. This hypothesis is partly based on the observation of the relationship between schizophrenia and diabetes and the finding that lean drug-naive schizophrenic patients display hepatic insulin resistance. Intriguingly, animal studies suggest a key role for pre-autonomic neurons in the hypothalamus in the regulation of hepatic glucose production and hepatic insulin sensitivity through sympathetic as well as parasympathetic outflow via the brain stem nuclei to the liver. This suggests an association between dopamine and insulin sensitivity. We want to elucidate the role of dopamine in the regulation of insulin sensitivity through a dopamine depletion challenge. This role may be important since dopamine modulating medication is widely prescribed for disorders as for instance ADHD, Parkinson and schizophrenia.

Study objective

We would like to eludicate the role of dopamine on glucose metabolism.

Study design

The insuline sensitivity will be analyised in a group of 10 healthy subjects, by means of two hyperinsulinemic euglycemic clamps. One of these clamps will be performed after dopamine depletion with AMPT.

Intervention

One of the clamps will be performed after dopamine depletion with AMPT.

Study burden and risks

Stabile isotopes are not radioactiev and are therefor harmless. AMPT can cause sleepiness, and rigidity of muscles. Patients will be in hospital for about 7 hours.

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 between 18 and 35

Exclusion criteria

1. Type I and II diabetes mellitus or any other chronic disease
2. Renal insufficiency or elevated liver enzymes
3. Family history of type II diabetes mellitus.
4. Primary dyslipidemia
5. Use of any drugs
6. Alcohol consumption in excess of 3 units per day or in the last 3 days before the clamp
7. History of drug abuse
8. Performance of vigorous exercise
9. History of psychiatric disorders

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2008
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Actrapid insuline
Generic name:	Insuline
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Demser

Generic name:	metyrosine

Ethics review

Approved WMO Date:	07-04-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2008-006142-25-NL
CCMO	NL19322.018.08