The effects of intranasal insulin on glucose metabolism in healthy men.

No registrations found.

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

Summary

ID

NL-OMON29342

Source
NTR

Brief title
N/A

Health condition

Diabetes Mellitus type II (DM II)
glucose metabolism/glucose metabolisme

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Endocrinology and Metabolism
Source(s) of monetary or material Support: Academic Medical Center (AMC), Department of Endocrinology and Metabolism

Intervention

Outcome measures

Primary outcome

Endogenous glocose production.

Secondary outcome

Insulin concentration in the CSF.

Study description

Background summary

Insulin is mainly known for its peripheral effects on the metabolism of glucose, fat and protein. The role of insulin signaling in the brain is only incompletely understood. To best way to study the effects of insulin in the brain, with low levels of insulin in the systemic circulations, is by administering it intranasally.

10 healthy male subjects will be studied twice, after administration of intranasal insulin and placebo. Glucose metabolism will be measured in the basal state and after administration of insulin/placebo, using stable isotopes. An intraspinal catheter will be inserted during the insulin study-day to measure the concentration of insulin in the CSF.

Study objective

We hypothesize that administration of intranasal insulin:

1. Inhibits endogenous glucose production, indepently of systemic insulin;

2. Increases the insulin concentration in the cerebrospinal fluid (CSF).

Study design

Every 10 - 30 minutes after intranasal insulin/placebo.

Intervention

Each subject will be studied twice. Intranasal insulin and placebo will be administered. Glucose metabolism will be measured using stable isotopes. An intraspinal catheter will be inserted during the insulin-study day to measure the concentration of insulin in the CSF.

Contacts

Public
Academic Medical Centre (AMC)
Department of Endocrinology & Metabolism

F5-162

N.M. Lammers
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5662663
Scientific
Academic Medical Centre (AMC)
Department of Endocrinology & Metabolism
F5-162

N.M. Lammers
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5662663

Eligibility criteria

Inclusion criteria

1. Lean healthy male volunteers;

2. Age 18-35 years;

3. BMI 20-25 kg/m2;

4. Normal oral glucose intolerance test according to the ADA-criteria.

Exclusion criteria

1. Any medication or substance use;

2. DM II;

3. Smoking;

4. Alcohol abuse (>3/day);

5. Lipid disorders, renal insufficiency, elevated liver enzymes or TSH;

6. Bleeding disorders;

7. Prior surgery of the nose and/or septum;

8. Allergic rhinitis;

9. Known allergies to antibiotics, used as prophylaxis in this study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-09-2009
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	NL1884
NTR-old	NTR1998
Other	METC Academic medical center : MEC 09/121
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A