

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

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To study the role of central insulin on glucose metabolism.

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

## Summary

### ID

NL-OMON33430

### Source

ToetsingOnline

### Brief title

intranasal insulin & glucose metabolism

### 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:** glucose, insulin, intranasal, metabolism

## Outcome measures

### Primary outcome

Endogenous glucose production.

### Secondary outcome

Insulin concentration in de cerebrospinal fluid

glucoregulatory hormones

## Study description

### Background summary

Recent animal studies have shown that insulin signaling in the central nervous system plays an important role in regulating the endogenous glucose (EGP) production by the liver. This seems to be mediated via insulin receptors in the hypothalamus. Activation of these receptors is needed for appropriate inhibition of the EGP during hyperinsulinemia. This means that insulin resistance of the hypothalamus might play a role in the pathophysiology of type 2 diabetes mellitus.

### Study objective

To study the role of central insulin on glucose metabolism.

### Study design

A randomised, cross-over study in 10 healthy men. They will be studied twice: after administration of intranasal insulin and administration of intranasal sterile water. Endogenous glucose production will be measured using stable isotopes. A lumbar drain will be placed for measurement of insulin concentrations in the cerebrospinal fluid, after administration of intranasal insulin.

### Intervention

intranasal administration of insulin vs sterile water

### Study burden and risks

Stable isotopes are not radioactive and are therefore harmless.

Previous studies have shown that intranasal insulin does not reach the systemic circulation. Severe hypoglycaemia is therefore not expected. Moreover, glucose measurements will be performed at 5 minutes intervals at the bedside.

We do not expect any complications during and after lumbar drain placement.

Risks of complications are minimized (see E7).

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Healthy men, ages between 18 and 35 years, BMI between 20 and 25 kg/m<sup>2</sup>, with a normal oral glucose tolerance test.

## Exclusion criteria

- \* any medication or substance use
- \* diabetes mellitus II (DM II) in first degree family members
- \* smoking
- \* alcohol abuse ( >3/day)
- \* lipid disorders, renal insufficiency, elevated liver enzymes or TSH
- \* bleeding disorders
- \* prior surgery of the nose and/or septum
- \* allergic rhinitis
- \* known allergies to antibiotics, used as prophylaxis in this study

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2009
Enrollment:	10
Type:	Anticipated

### Medical products/devices used

Product type:	Medicine
Brand name:	Actrapid insulin
Generic name:	insulin
Registration:	Yes - NL outside intended use

## Ethics review

Approved WMO

Date: 09-04-2010

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	EUCTR2009-012899-26-NL
CCMO	NL28322.018.09