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

Gepubliceerd: 09-09-2009 Laatst bijgewerkt: 18-08-2022

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).

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29342

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Endocrinology and Metabolism
Overige ondersteuning: Academic Medical Center (AMC), Department of Endocrinology and Metabolism

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Endogenous glocose production.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

Every 10 - 30 minutes after intranasal insulin/placebo.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-01-2009
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1884
NTR-old	NTR1998
Ander register	METC Academic medical center : MEC 09/121
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A