Het effect van een DPP-4 remmer op de reactie van het lichaam bij een hypoglykemie bij patiënten met type 1 diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25642

Source
NTR

Brief title
DARE

Health condition

EN - NL
Type 1 diabetes mellitus - type 1 diabetes mellitus
Hypoglycaemia - hypoglykemie
Glucagon - glucagon

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Merck Sharp & Dohme

Intervention

Outcome measures

Primary outcome

Glucagon response to insulin induced hypoglycaemia measured as AUC (area under the curve).

Secondary outcome

1. Other counterregulatory hormone responses to insulin induced hypoglycaemia measured as AUC;

2. Symptomatic hormone responses to insulin induced hypoglycaemia.

Study description

Background summary

Hypoglycaemia is a well-known complication of insulin treated diabetes. The counterregulatory response to hypoglycaemia, with glucagon as the most important mediator, is initially diminished within a few years of onset of Type 1 diabetes and subsequently lost and thus increasing the risk of hypoglycaemia. DPP-4 inhibitors augment the glucagon response to insulin-induced hypoglycaemia in type 2 diabetes. We hypothesize that treatment with a DPP-4 inhibitor in patients with type 1 diabetes will recover the alpha cell response to hypoglycaemia.

Study objective

We hypothesize that treatment with a DPP-4 inhibitor will enhance the glucagon response to hypoglycaemia in patients with type 1 diabetes.

Study design

0, 6 and 12 weeks.

Intervention

The 16 type 1 patients will be randomised to one of two treatment sequences: DPP-4 inhibitor followed by placebo or placebo followed by a DPP-4 inhibitor. Each treatment period lasts 6 weeks, so all patients will receive treatment for 12 weeks in total. Induction of hypoglycaemia will take place at 0 weeks, 6 weeks and 12 weeks to determine the glucagon response.

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Eligibility criteria

Inclusion criteria

1. Male;

2. Age 18-40 years;

3. Type 1 Diabetes Mellitus 5-20 years duration;

4. C-peptide negative;

5. Willing and able to give written informed consent.

Exclusion criteria

1. Impaired awareness of hypoglycaemia;

2. BMI > 27 kg/m2;

3. Evidence of severe diabetes complications (autonomic neuropathy, macroalbuminuria, proliferative retinopathy);

4. Acute illness within 3 months before the study;

5. Significant renal impairment (creatinine clearance <50ml/min);

6. Use of beta-adrenoreceptor blockers;

7. Cardiac history (previous arrhythmia);

8. History of epilepsy.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion

Date:	08-10-2010
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	NL2446
NTR-old	NTR2563
Other	MEC AMC : 10/202
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A