Effect of adding vildagliptin to start of insulin treatment in patients with type 2 diabetes.

No registrations found.

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

Summary

ID

NL-OMON29400

Source
NTR

Health condition

Diabetes

Sponsors and support

Primary sponsor: UMCUtrecht
Source(s) of monetary or material Support: Novartis B.V.

Intervention

Outcome measures

Primary outcome

Dose of insulin necessary for glycaemic control.

Secondary outcome

Hypoglycemia
Weight

Blood pressure
Glycaemic variability
Glucagon dynamics
Lipids, markers of vascular function and inflammation and coagulation
Skin autofluorescence (AGE-level)

Study description

Background summary

Type 2 diabetes is characterized by progressive beta cells, causing deterioration of beta cell function. Due to this progressive nature of the disease, at a certain point oral glucose lowering drugs in combination with diet cannot establish normoglycemia anymore. At this poit the patient should start insulin treatment. Usually once daily long-acting insulin is then started.

Insulin treatment usually results in weight gain and increases the change for hypoglycemia. A lot of research looks into the effect of oral glucose lowering drugs added to insulin on HbA1c, as a measure of glycemic regulation. Studies with DDP4-inhibitors showed, significant reduction of HbA1c , when added to insulin, where the insulin regimen was kept the same. This was seen in combination with less hypoglycemias. But in daily clinical practice insulin regimens will be modified according to glycemic variation, and not HbA1c but insulin doses are the primary effect.
The mechanism of better glycemis control of combination of DPP4-inhibitors and insulin includes a glucose dependent insulin secretion (in contrast to for instance sulfonyl ureum derivates, which give a constant beta cel stimulation, unrelated to glucose) with the DPP4-inhibitors, as well as decreases in glucagon production (hyperglucagonemia is a problem in diabetes). Resulting in less endogeneous glucose production.

The primary effect of this study will be the necessary dose of insulin required. Secundary end points are parameters related to glucose regulation (continuous glucose measurement CGMS), insulin and glucagon levels after standardized mixed meal tests, vascular effects (24 hours blood pressure measurement, lipids), changes in advanced glycation end products (AGEs, measured by skin autofluorescence).

Study objective

Vildagliptin lowers insulin requirement, through effects on insulin and glucagon secretion.

Study design

0, 8, 16 weeks.

Intervention

Vildagliptin versus placebo, added to start of once daily insulin in combination with a standardized dose of metformin.

Contacts

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Eligibility criteria

Inclusion criteria

1. Type 2 diabetes;

2. Failing on oral agents;

3. BMI 25-35;

4. HbA1c 7.0-9.0 %;

5. Age 25-75 y.

Exclusion criteria

1. Pregnant women or women in the fertile period of life without adequate birth-control;

2. Type I DM, or secondary form of DM (eg pancreatic injury, prednisone induced);

3. Acute metabolic complications (severe hypoglycaemia, hospital-admission for uncontrolled Keto-acidosis) during the last 6 months;

4. Severe cardiac (LVEF < 30%) or hepatic (transaminases > 3 times elevated) or a history of hepatic failure, or renal impairment (creatinine clearance <50 ml/min).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	21-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37974
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1905
NTR-old	NTR2022
CCMO	NL26046.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37974

Study results

Summary results
N/A