

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29400

Bron

NTR

Aandoening

Diabetes

Ondersteuning

Primaire sponsor: UMCUtrecht

Overige ondersteuning: Novartis B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Dose of insulin necessary for glycaemic control.

Toelichting onderzoek

Achtergrond van het onderzoek

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 point 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 DPP4-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 hypoglycemia. 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 glycemic control of combination of DPP4-inhibitors and insulin includes a glucose dependent insulin secretion (in contrast to for instance sulfonyl ureum derivatives, which give a constant beta cell stimulation, unrelated to glucose) with the DPP4-inhibitors, as well as decreases in glucagon production (hyperglucagonemia is a problem in diabetes). Resulting in less endogenous glucose production.

The primary effect of this study will be the necessary dose of insulin required. Secondary 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).

Doel van het onderzoek

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

Onderzoeksopzet

0, 8, 16 weeks.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Postbus 85500
W.L. Greven
Utrecht 3508 GA
The Netherlands

Wetenschappelijk

Postbus 85500
W.L. Greven
Utrecht 3508 GA
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Type 2 diabetes;
2. Failing on oral agents;
3. BMI 25-35;
4. HbA1c 7.0-9.0 %;
5. Age 25-75 y.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2009
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	21-09-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37974
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A