Prevention of weight gain when starting insulin therapy in patients with type 2 diabetes.

Gepubliceerd: 08-03-2011 Laatst bijgewerkt: 13-12-2022

In the first 6 months Liraglutide affects weight more than CBT, but CBT provides weight maintenance after 12 months.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20833

Bron
NTR

Aandoening

type 2 diabetes, insulin therapy, adults, overweight, obesity, weight, glyceamic control, blood glucose, lifestyle, diabetes self management, cognitive behavioral therapy, liraglutide, GLP-1

type 2 diabetes, insuline therapie, volwassenen, overgewicht, obesitas, gewicht, glycemische controle, bloedglucose, bloedsuiker, leefstijl, diabetes zelfzorg, cognitieve gedragstherapie, liraglutide, GLP-1

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Erasmus Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measure is weight change (kg). Mean weight change from baseline to month 6 in the liraglutide arm and CBT arm will be compared. In addition, weight change will be examined at month 12.

Toelichting onderzoek

Achtergrond van het onderzoek

Most people with type 2 diabetes on maximum oral glucose lowering drugs need insulin therapy to improve glycaemic control. However, insulin induced weight gain is undesirable since the majority of this population already is overweight. Weight gain is associated with insulin resistance and increased risk of cardiovascular complications. Therefore, insulin therapy associated weight gain should be prevented. In our study we compare the preventive effects on insulin induced weight gain of two different therapies that are associated with weight loss in patients with type 2 diabetes: Liraglutide and Cognitive Behavioral Therapy.

Doel van het onderzoek

In the first 6 months Liraglutide affects weight more than CBT, but CBT provides weight maintenance after 12 months.

Onderzoeksopzet

Baseline, 3 months, 6 months and 12 months.

Onderzoeksproduct en/of interventie

The interventions are 26 weeks liraglutide or 26 weeks cognitive behavioral therapy added to insulin therapy and usual care.

Liraglutide is a long-acting glucagon-like peptide-1 (GLP-1) analog that provides glycemic control and avoids hypoglycemia without the additional weight gain that characterizes many other glucose lowering drugs. The dose of liraglutide is 0.6 mg daily in the first week, 1.2 mg daily in the second week and 1,8 mg daily from the third week by subcutaneous injection.

The cognitive behavioral treatment consists of 8 individual meetings (45 minutes each) and 4 group meetings (90 minutes each) with a psychologist. In these meetings dysfunctional cognitions that lead to unhealthy behavior are gradually uncovered, challenged and changed

into more functional cognitions that are more likely to lead to healthy behavior.

Contactpersonen

Publiek

Postbus 2040
Hanneke Buijks
Erasmus MC
Afd. Medische Psychologie & Psychotherapie
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7031942

Wetenschappelijk

Postbus 2040
Hanneke Buijks
Erasmus MC
Afd. Medische Psychologie & Psychotherapie
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7031942

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Type 2 diabetes and requiring insulin therapy (novorapid, novomix, levemir);

2. On maximal oral glucose lowering drugs;

3. BMI > 25 kg/m^2;

4. GFR (renal function) > 60 µ mol/l;

5. Age 18-75;

6. Ability to speak Dutch or English.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Eating disorder or major depression;

2. Alcohol abuse;

3. History of pancreatitis & thyroid disorders;

4. Inflammatory Bowel Syndrome;

5. Pregnancy or lactating;

6. Use of insulin;

7. Known allergy to Liraglutide;

8. Use of Liraglutide within 3 months before entering study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	118
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL2670
NTR-old	NTR2798
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A