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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20833

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

We will examine the insulin consumption and the cost-effectiveness of both treatments. Furthermore, laboratory variables are measured to determine parameters of participants' health during the study. In addition, diabetes specific psychological parameters are assessed to examine if CBT positively affects psychological well being.

Study description

Background summary

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.

Study objective

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

Study design

Baseline, 3 months, 6 months and 12 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. On maximal oral glucose lowering drugs;

3. BMI > 25 kg/m²;

4. GFR (renal function) > 60 µ mol/l;

5. Age 18-75;

6. Ability to speak Dutch or English.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	118
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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

Study results

Summary results
N/A