Onderzoek naar de effecten van het medicijn liraglutide bij patiënten met een type suikerziekte (diabetes) die veroorzaakt is door het gebruik van antipsychotische medicijnen.

No registrations found.

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

Summary

ID

NL-OMON24018

Source
NTR

Brief title
GRADUATE

Health condition

anti-psychotic-drug diabetes mellitus
diabetes mellitus veroorzaakt door antipsychotica

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: NovoNordisk

Intervention

Outcome measures

Primary outcome

The primary end point of this study is the change in HbA1c from baseline to ‘end of trial’

Secondary outcome

Efficacy

o Change in fasting glucose

o Change in body weight and BMI

o Change in waist and hip circumferences and waist hip ratio

o Change in blood pressure

o Change in lipid levels

o Change in abdominal fat content (abdominal CT-scan)

Safety/ Feasibility

o Compliance with use of drug liraglutide (number of injection vials used)

o (Serious) Adverse events during liraglutide use

Change in psychiatric symptoms

o CAPE-score

o CGI- score

o PANS-score

Patient-reported outcomes

o PAID (problem areas in diabetes)

o SF-12

o DTSQ

o EQ5D

Study description

Background summary

N/A

Study objective

Liraglutide is an effective and safe treatment modality in metformin-treated patients suffering from schizophrenia with anti-psychotic drugs-related diabetes mellitus.

Study design

0, 6, 12, 24 weken

Intervention

• To explore the efficacy of liraglutide in terms of glycaemic control assessed by HbA1c.

b. Secondary Objectives

• To explore the effect of liraglutide on cardiovascular risk factors, body weight and intra-abdominal fat content using CT-scans in obese patients with antipsychotics-associated diabetes mellitus

• To explore feasibility of liraglutide in the treatment of antipsychotic drugs- associated diabetes and obesity in patients suffering from severe mental illness in terms of compliance with the treatment regimen

• To explore possible change in psychiatric symptoms during treatment with liraglutide in severe mental illness using questionnaires.

Contacts

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Eligibility criteria

Inclusion criteria

• Informed consent obtained before any trial related activities

• Males or females aged 18 years or older

• Diabetes mellitus developed while on anti-psychotic drugs for at least six months

• Use of metformin for the treatment of diabetes

• HbA1c >7.0% - ≤ 10.0 mmol/l (53 – 86 mmol/mol)

• BMI 30 – 45 kg/m2

• Regarded capable to understand and follow the protocol

Exclusion criteria

• Any type of diabetes present before the use of anti-psychotic drugs

• Use of glucose-lowering medication other than metformin

• No cardiovascular event in the last 6 months

• Reduced cardiac function (LVEF < 30%)

• No evidence of active retinopathy

• No controlled or uncontrolled hypertension (systolic pressure > 180 mm Hg and/or diastolic pressure > 100 mm Hg

• Renal failure (MDRD < 30 ml/min)

• Liver function abnormalities (ALT and/or AST > 3 times the upper limit of normal)

• History of chronic pancreatitis or previous acute pancreatitis

• Known or suspected hypersensitivity to trial product(s) or related product(s)

• Female of child-bearing potential who is pregnant, breast-feeding or intend to become pregnant or is not using adequate contraceptive methods

• Participation in another trial or receipt of any investigational medicinal product within 90 days prior to screening

• Subjects who are considered incapable for inclusion by their physicians

• Subjects who are considered inadequate for liraglutide administration themselves or lack network of support

• Subjects who are actively suicidal

• Recurrent use of corticosteroids

• Personal or family history of medullary thyroid carcinoma and patients with multiple endocrine neoplasia type 2 (MEN2)

• Known or suspected abuse of alcohol or narcotics

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014
Enrollment:	50
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	NL4111
NTR-old	NTR4352
Other	HW de Valk : U1111-1144-0576
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A