Liraglutide for low-responders after bariatric surgery

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To study the effect of Liraglutide (3.0 mg daily) on 9-month weight loss in low responders 3-months after bariatric surgery.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49525

Source
ToetsingOnline

Brief title
LIBAR

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
bariatric surgery, Obesity

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Nederlandse Obesitas Kliniek
Source(s) of monetary or material Support: Nederlandse Obesitas Kliniek,Novo Nordisk

Intervention

Keyword: bariatric surgery, GLP-1, low-reponders, weight loss

Outcome measures

Primary outcome

The primary objective is to study the effect of Liraglutide (3.0 mg daily) on

9-month weight loss in low responders after bariatric surgery.

Secondary outcome

There are three secondary objectives:

a) To describe the persistence of therapy and the average daily dose patients

used

b) To describe the gastro-intestinal symptoms and eating habits of the study

group

c) To study the weight loss up to 36 months after surgery

Study description

Background summary

Compared to life-style intervention programs, bariatric surgery has proven to be a superior treatment for morbid obesity. However, in 20 * 30% of the patients sufficient weight loss is not achieved (low responders) or weight regain occurs. Secondary and/or tertiary bariatric procedures can lead to successful weight loss and resolution of comorbid conditions, however morbidity and mortality rates of these procedures are high. Therefore, additional pharmacotherapy in post-bariatric patients has been suggested. Liraglutide is one of the medications that might improve outcome in the post-bariatric population.

Liraglutide is a Glucagon-like peptide-1 (GLP-1) receptor analogue developed to treat type 2 diabetes. It causes glucose-dependent insulin secretion and promotes satiety and inhibits glucagon secretion. In obese (non-bariatric) patients, Liraglutide has shown to improve glycemic control, decrease blood pressure, lower cardiovascular risk and decrease body weight.
There are only a few small retrospective trials assessing the effect of additional pharmacotherapy in low responders after bariatric surgery. These trials show promising results, with weight loss up to 9.7 % and limited side-effects.

Study objective

To study the effect of Liraglutide (3.0 mg daily) on 9-month weight loss in low responders 3-months after bariatric surgery.

Study design

Pragmatic trial.

Intervention

Addition of Liraglutide 3.0 mg daily for 6 months to standard care.

Study burden and risks

The burden of participation consists of extra usage of medication which patients have to administer subcutaneously daily, the extra consultations and questionnaires. The risk consists of side-effects, of which we think gastro-intestinal side-effects will be most frequent.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patient is *18 and <75 years old
* BMI before surgery was * 35.0 kg/m2
* Patient is treated with group consultation at the NOK
* Patient has undergone a primary Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG)
* Patient is in the lowest %TWL quartile, 3 months after surgery and will be enrolled in the plus module.

Exclusion criteria

* Type 1 or type 2 diabetes
* Decreased renal function (creatinine clearance < 30 ml/min)
* Liver failure (all)
* Congestive heart failure or angina pectoris NYHA class III and IV
* Malignancy in history
* Pancreatitis (in history)
* Pregnancy / breast-feeding
* Inflammatory Bowel Disease
* Thyroid malignancy in history
* Use of warfarin or other coumarin derivates

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Saxenda
Generic name:	Liraglutide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-12-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-01-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
EudraCT	EUCTR2020-000548-71-NL
CCMO	NL73067.096.20