Visualizing beta cells in patients with remission of T2DM after bariatric surgery

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The primary objective is to evaluate the difference in 68Ga-exendin tracer accumulation in the pancreas of patients with and without complete resolution of T2DM after RYGB by quantitative analysis of PET images.

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON42279

Source
ToetsingOnline

Brief title
Visualizing beta cells after bariatric surgery

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal therapeutic procedures

Synonym
Type 2 Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bariatric surgery, beta cells, Type 2 diabetes

Outcome measures

Primary outcome

The main parameter of the study is the quantitative assessment of pancreatic

68Ga-NODAGA-exendin-4 uptake in responders and non-responders after RYGB by

PET/CT.

Secondary outcome

The secondary endpoint is to the correlation between 68Ga-exendin tracer

accumulation and beta cell function of the patients.

Study description

Background summary

In order to evaluate the difference in beta cell mass in patients with and without complete resolution of type 2 diabetes mellitus (T2DM) after Roux en Y gastric bypass (RYGB) we aim to compare quantitative PET imaging of the pancreas between these patient groups.

Study objective

The primary objective is to evaluate the difference in 68Ga-exendin tracer accumulation in the pancreas of patients with and without complete resolution of T2DM after RYGB by quantitative analysis of PET images.

Study design

Dual center phase 1 study we will assess the difference in beta cell mass between obese T2D patients with or without complete resolution of T2D after bariatric surgery by quantitative analysis of 68Ga-NODAGA-exendin-4 PET/CT images.

Study burden and risks

Injection of the radiopharmaceutical may theoretically result in nausea and headache as has been reported for (much higher doses) of Byetta® in therapy studies. In addition, single cases of low blood pressure and low blood glucose levels have been described. Although low blood glucose levels only occurred after accidental heavy overdosing of Byetta®, patients will be closely monitored. However, in a previous study (CPOP-EX), we did not observe any side or adverse effects after 111In-DTPA-[K40]-Exendin 4 injection for all 20 patients included.
The expected radiation exposure will not exceed 5 mSv and is therefore considered minimal to little. However, if the technique would indeed allow sensitive and specific visualization and quantification of beta cell mass in patients after RYGB, the impact on evaluation of bariatric surgery as an alternative therapy for T2DM would be very high.

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

Responders:
- Obese T2D patient who has undergone RYGB at least one year earlier
- Signed informed consent
- Complete resolution of T2DM after surgery (HbA1c in normal range, fasting glucose <100 mg/dl for at least 1 year in the absence of active pharmacologic therapy or ongoing procedures);non-responders:
- Obese T2D patient who has undergone RYGB at least one year earlier
- Signed informed consent
- No complete resolution of T2DM after surgery (still requires treatment with oral hypoglycaemic agents or insulin)

Exclusion criteria

- Previous treatment with synthetic Exendin (Exenatide, Byetta®) or Dipeptidyl-Peptidase IV inhibitors
- Breast feeding
- Pregnancy or the wish to become pregnant within 6 months
- Calculated creatinine clearance below 40ml/min
- Age < 18 years
- No signed informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-11-2015

Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	68Ga-NODAGA-exendin-4
Generic name:	nvt

Ethics review

Approved WMO Date:	07-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-02-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-04-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2014-004317-90-NL
CCMO	NL51058.091.14