Visualizing beta cells in patients with a history of gestational diabetes

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This study has been transitioned to CTIS with ID 2024-520392-27-00 check the CTIS register for the current data. The primary objective is to evaluate the difference in 68Ga-exendin tracer accumulation in the pancreas of women with and without a…

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

Summary

ID

NL-OMON47071

Source
ToetsingOnline

Brief title
GLP-1-gestational

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Gestational diabetes, pregnancy diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Nucleaire geneeskunde en radiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Beta cells, exendin, gestational diabetes, PET

Outcome measures

Primary outcome

The main study parameter is the difference between the uptake of

68Ga-NODAGA-exendin-4 (measured by quantification/quantitative analysis of PET

images) in the pancreas of women with and without a history of gestational

diabetes mellitus as a measure for beta cell mass.

Secondary outcome

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

accumulation and beta cell function of the subjects.

Study description

Background summary

In order to evaluate the difference in beta cell mass in women with and without a history of gestational diabetes mellitus (GDM) we aim to compare quantitative PET imaging of the pancreas between these groups.

Study objective

This study has been transitioned to CTIS with ID 2024-520392-27-00 check the CTIS register for the current data.

The primary objective is to evaluate the difference in 68Ga-exendin tracer accumulation in the pancreas of women with and without a history of GDM by quantitative analysis of PET images.

Study design

Women with a history of GDM and women without a history of GDM as a control group will be recruited at the Radboudumc and by advertisement. After recruitment of the participating individuals, all women will undergo an

enrolment check at the Department of Radiology and Nuclear Medicine at the Radboudumc consisting of a medical interview and a physical examination performed by a qualified physician. Blood samples will be taken for laboratory checks (glucose, HbA1c, C-peptide, creatinine, ALAT, ASAT). On the same day an oral glucose tolerance test will be performed.
At the second visit, a PET/CT scan will be performed at the Radboudumc. 68Ga-NODAGA-exendin-4 will be administered to all participants. 1 hour after injection a PET/CT scan will be performed.

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, although this has not been observed in imaging studies so far. In addition, single cases of low blood pressure and low blood glucose levels have been described after application of therapeutic or higher doses of Byetta®. 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. Furthermore, in a study of Christ et al. no side effects were observed in 30 patients with endogenous hyperinsulinemic hypoglycemia after injection of 111In-DTPA-exendin-4. The expected radiation exposure will not exceed 5 mSv and is therefore considered minimal to little. However, sensitive and specific visualization and quantification of beta cell mass with this technique would be highly relevant for further understanding of the pathophysiology of type 2 diabetes and the development of new treatment options.

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

Inclusion criteria (women with history of GDM);- Pregnancy with diagnosis of GDM, within the last 5 years;- No other previous pregnancies;- Complete resolution of GDM after delivery (HbA1c in normal range, fasting glucose < 100 mg/dl for at least 1 year in the absence of active pharmacologic therapy or ongoing procedures);- Signed informed consent;Inclusion criteria (women without history of GDM);- Pregnancy without problems in glucose homeostasis, within the last 5 years;- No other previous pregnancies;- No evidence of T2D at time of inclusion (HbA1c in normal range, fasting glucose < 100 mg/dl for at least 1 year in the absence of active pharmacologic therapy);- Insulin secretion-sensitivity index-2 (ISSI-2) >= 800 on oral glucose tolerance test;- Signed informed consent

Exclusion criteria

Exclusion criteria;- Previous treatment (within 6 months) with synthetic Exendin (Exenatide, Byetta®) or Dipeptidyl-Peptidase IV inhibitors;- Breast feeding;- Current pregnancy or the wish to become pregnant within 6 months;- Renal dysfunction (Calculated creatinine clearance below 40ml/min);- Liver disease defined as aspartate aminotransferase or alanine aminotransferase level of more than three times the upper limit of normal range ;- Age < 18 years;- Incapacitated;- No signed informed consent

Study design

Design

Study phase: 2

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:	Recruiting
Start date (anticipated):	31-03-2017
Enrollment:	24
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	25-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-04-2018
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
EU-CTR	CTIS2024-520392-27-00
EudraCT	EUCTR2016-000794-20-NL
CCMO	NL56938.091.16