Effect of Gelofusine on 111In-DTPA-AHX-Lys40-Exendin 4 uptake in the kidney

Published: 09-02-2015
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Primary Objective: The primary objective is to determine whether the administration of Gelofusine will reduce the kidney uptake of 111In-labeled exendin in humans by enhancing the excretion of 111In-labeled exendin. These highly relevant data can...

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

Summary

ID

NL-OMON41060

Source
ToetsingOnline

Brief title
Effect of Gelofusine on GLP1-receptor imaging

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: BetaCure project 602810

Intervention

Keyword: beta cell, Gelofusine, radiopeptides, SPECT

Outcome measures

Primary outcome

The main study parameter is the renal uptake of 111In-DTPA-[K40]-Exendin 4

based on quantitative SPECT imaging with and without co-infusion of Gelofusine.

Secondary outcome

The secondary study parameter is the pancreatic uptake of

111In-DTPA-[K40]-Exendin 4 based on quantitative SPECT imaging with and without

co-infusion of Gelofusine.

Study description

Background summary

We hypothesize that Gelofusine will reduce the kidney uptake of 111In-labeled exendin in humans by enhancing the excretion of 111In-labeled exendin.This has already been shown in rodents for this tracer and for other tracers (e.g.111In-Octreotide) in humans.

Study objective

Primary Objective:

The primary objective is to determine whether the administration of Gelofusine will reduce the kidney uptake of 111In-labeled exendin in humans by enhancing the excretion of 111In-labeled exendin.

These highly relevant data can potentially improve the interpretation of clinical quantitative SPECT and can have important implications for imaging of pancreatic beta cell mass in diabetes patients as well as therapeutic decision making for patients with insulinomas or congenital hyperinsulinism.

Secondary Objective(s):
Determine whether the administration of Gelofusine affects pancreatic uptake of 111In-labeled exendin based on quantitative analysis of SPECT images.

Study design

Cross-over study to prove that the administration of Gelofusine reduces the kidney uptake of 111In-labeled exendin in healthy, adult volunteers.

Study burden and risks

All individuals will undergo physical examination and blood sampling for standard laboratory parameters (first visit). Prior to SPECT acquisition, participants will be injected with111In-DTPA-[K40]-Exendin 4. Patients will undergo two acquisitions: one time in combination with saline (control) and the second time in combination with Gelofusine.Injection of the radiopharmaceutical may theoretically result in nausea and headache as has been reported for (much higher doses of) Byetta® in therapeutic studies. In addition, single cases of low blood pressure and low blood glucose levels have been described after accidental heavy overdosing of Byetta®. However, in another study (CPOP-EX), we did not observe any side or adverse effects after 111In-DTPA-[K40]-Exendin 4 injection in 20 patients. The expected radiation exposure will not exceed 10 mSv and is therefore considered minimal to little. Bruising may occur after venous puncture. In conclusion, the risk of adverse events during this study is very low and, therefore, the additional risk for volunteers participating to this study is considered to be moderate.
Gelofusine is a registered medicinal product. Although not frequently reported, side effects are allergy reactions like skin reactions and anaphylaxis, fever and chills. Therefore, participants will be closely monitored.
If we are able to reduce the kidney/pancreas uptake ratio, these data will have an important impact on the interpretation of clinical quantitative SPECT, which in turn will have important implications for our understanding of the course of diabetes as well as therapeutic decision making for patients with insulinomas or congenital hyperinsulinism.

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

* ><= 18 years
* <<= 60 years
* Normal renal function (creatinine clearance > 90mL/min according to the formula of Cockroft and Gault)
* Normal glucose regulation (HbA1c 53 /mol (7%))
* BMI 17>30

Exclusion criteria

* Use of any medication affecting renal function
* Known hypersensitivity to one of the substances used
* Hypertension
* Oedema
* Hypervolaemia
* Heart failure
* Pregnancy or the wish to become pregnant within 3 months after participation of the study.
* Lactation
* History of anaphylaxis
* Liver disease defined as aspartate aminotransferase or alanine aminotransferase level more than 3 times the upper limit of normal range (45U/L)

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	111In-DTPA-[K40]-Exendin 4
Generic name:	N.v.t.
Product type:	Medicine
Brand name:	Gelofusine
Generic name:	N.v.t.
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	09-02-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	16-02-2015
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:	01-12-2015
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	EUCTR2014-003006-33-NL
CCMO	NL50233.091.14

Study results

Date completed:	05-07-2016
Actual enrolment:	11