

# Effect of Gelofusine on <sup>111</sup>In-DTPA-AHX-Lys40-Exendin 4 uptake in the kidney

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**Primary Objective:** The primary objective is to determine whether the administration of Gelofusine will reduce the kidney uptake of <sup>111</sup>In-labeled exendin in humans by enhancing the excretion of <sup>111</sup>In-labeled exendin. These highly relevant data can...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Glucose metabolism disorders (incl diabetes mellitus)
<b>Study type</b>	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  $^{111}\text{In}$ -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  $^{111}\text{In}$ -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  $^{111}\text{In}$ -labeled exendin in humans by enhancing the excretion of  $^{111}\text{In}$ -labeled exendin. This has already been shown in rodents for this tracer and for other tracers (e.g.  $^{111}\text{In}$ -Octreotide) in humans.

### Study objective

Primary Objective:

The primary objective is to determine whether the administration of Gelofusine will reduce the kidney uptake of  $^{111}\text{In}$ -labeled exendin in humans by enhancing the excretion of  $^{111}\text{In}$ -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 <sup>111</sup>In-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 <sup>111</sup>In-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 with <sup>111</sup>In-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 <sup>111</sup>In-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

- \*  $\geq 18$  years
- \*  $\leq 60$  years
- \* Normal renal function (creatinine clearance  $> 90\text{mL/min}$  according to the formula of Cockcroft and Gault)
- \* Normal glucose regulation (HbA1c  $\leq 53 \text{ mmol/mol}$  (7%))
- \* BMI  $17 < \text{BMI} \leq 30$

### 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