# Controlling Glucose during Elective hip Surgery To study the influence on Coagulation.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26959

**Source**
NTR

**Brief title**
CONGEST trial

**Health condition**

peri-operative glycemic control; hip surgery; liraglutide

### Sponsors and support

**Primary sponsor:** Academic Medical Centre Amsterdam
**Source(s) of monetary or material Support:** Novo Nordisk

### Intervention

### Outcome measures

**Primary outcome**

The difference in mean glucose between the CG and the LG at day 3 after surgery.

**Secondary outcome**

The difference in mean glucose between CG and the LG during surgery, the between group difference in mean coagulation parameters, the between group difference in mean glucagon and cortisol levels and the difference in proportion of patients who have glucose values in fasting state below 7.8 mmol/l at day 3 after surgery.

# Study description

### Background summary

Study carried out in the Netherlands.

### Study objective

To investigate the efficacy of liraglutide to lower glucose and to influence coagulation activation during and after hip surgery.

### Study design

N/A

### Intervention

1. Liraglutide 0.6 mg once-daily s.c., intensified to 1.2mg after one day if there is no nausea on the starting dose;

2. Placebo, once-daily, s.c.

Blood samples will be obtained for assessment of glucose, coagulation parameters (PAI-1, PAP, F1+2, FVIII, TAT, ETP, PT, APTT, vWF, D-Dimer and antithrombin levels), glucagon and cortisol levels at three timepoints: before surgery, 2 hours post surgery and at day 3 after surgery.

# Contacts

**Public**
Academic Medical Center<br>
Dpt Internal Medicine F4-2257<br>
POBox 22660
M.K. Sechterberger

Amsterdam 1100 DD
The Netherlands
**Scientific**
Academic Medical Center<br>
Dpt Internal Medicine F4-2257<br>
POBox 22660
M.K. Sechterberger
Amsterdam 1100 DD
The Netherlands

# Eligibility criteria

## Inclusion criteria

1. Signed informed consent;

2. Planned for elective hip replacement surgery;

3. Age 18-75 years inclusive;

4. Fraxiparine or Dabigatran used as anticoagulant drug.

## Exclusion criteria

1. Known type 1 or type 2 diabetes mellitus;

2. Oral corticosteroid use;

3. Use of a Vitamin K antagonist (VKA) as anticoagulant drug;

4. Revision hip replacement;

5. Known coagulation disorders;

6. Peripheral nerve block peri-operative;

7. Known active cancer of the subject;

8. History of chronic pancreatitis or idiopathic acute pancreatitis;

9. Impaired liver function, defined as alanine aminotransferase (ALAT) >2.5 times upper normal limit;

10. Impaired renal function defined as serum-creatinine > 133 µmol/L for males and > 115 µmol/L for females;

11. Females of child bearing potential who are pregnant, breast-feeding or intend to become pregnant or are not using adequate contraceptive methods (adequate contraceptive measures as required by local law or practice);

12. Known or suspected allergy to trial product(s) or related products;

13. Any condition that the local investigator feels would interfere with trial participation or the evaluation of results.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 06-08-2012 |
| Enrollment: | 36 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 30-07-2012 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 37363
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3404 |
| NTR-old | NTR3547 |
| CCMO | NL38327.018.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON37363 |

# Study results

**Summary results**
N/A