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

Gepubliceerd: 30-07-2012 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26959

Bron
NTR

Verkorte titel
CONGEST trial

Aandoening

peri-operative glycemic control; hip surgery; liraglutide

Ondersteuning

Primaire sponsor: Academic Medical Centre Amsterdam
Overige ondersteuning: Novo Nordisk

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Study carried out in the Netherlands.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-08-2012
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37363
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A