Controlling Glucose during Elective hip Surgery to study the influence on Coagulation

Published: 18-10-2011
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the purpose of this study is to investigate the efficacy of liraglutide to lower glucose and to influence coagulation activation during and after hip surgery

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

Summary

ID

NL-OMON37363

Source
ToetsingOnline

Brief title
CONGEST trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
hip surgery, hyperglycemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Novo Nordisk,Novo Nordisk Inc.

Intervention

Keyword: Coagulation, Glycemic Control, Hip surgery

Outcome measures

Primary outcome

Main study parameter will be the difference in mean glucose between both groups

at day 3 after surgery

Secondary outcome

Secundary study outcomes will be mean differences in coagulation parameters

(PAI-1, PAP, F1+2, FVIII, TAT, ETP, PT, APTT, vWF, D-Dimer and antithrombin

levels), cortisol and glucagon 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

During orthopedic surgery, the coagulation system is activated, resulting in a considerable risk of postoperative venous thromboembolism (VTE). Additionally, increased postoperative glucose levels (> 7.9 mmol/l) are related to an increased number of symptomatic VTE, independent of known diabetes mellitus and other confounders. Evidence is mounting that hyperglycemia during surgery due to stress of the procedure (*stress hyperglycemia*), leads to a hypercoagulable and hypofribinolytic state. No intervention studies have investigated the influence of glycemic control during hip surgery on coagulation activation. The most widely used method to apply glycemic control is intensive insulin therapy. This carries however an increased risk of hypoglycemia related mortality. As most hip surgery is elective, applying glycemic control using other glucose lowering agents with less risk to develop hypoglycemia is a possibility. A recent development in glucose lowering agents is the availability of incretins. Liraglutide, a human glucagon-like peptide (GLP-1) analogue, increases insulin secretion and decreases glucagon secretion in a glucose-dependent manner and is an approved drug in the management of

diabetes mellitus type 2.

Study objective

the purpose of this study is to investigate the efficacy of liraglutide to lower glucose and to influence coagulation activation during and after hip surgery

Study design

A prospective, randomized, double-blind, placebo-controlled trial

Intervention

The participants will be randomized to one of the two treatment groups, the liraglutide group (LG) or the control group (CG). Subjects in the LG will start one day prior to surgery with administration of liraglutide subcutaneously (s.c.) once daily, this will be continued until three days postoperatively. Start dosing will be 0.6 mg, this will be intensified to 1.2mg if there is no nausea on the starting dose. The CG will be given placebo s.c. one day prior to surgery until three days postoperatively. The study will end three days postoperatively.

Study burden and risks

The study will be conducted on patients who will undergo elective hip surgery. Informed consent will be obtained beforehand during the screening visit. The study will be performed peri-operatively, therefore no extra hospital visits are expected. Before induction of anaesthesia, 2 hours after surgery and three days after surgery blood samples will be obtained (a 2ml Sodium-Floride tube and three 2.7mL Sodium-Citrate-tubes and a 6mL heparin tube) to measure glucose, coagulation parameters, cortisol and glucagon levels.HbA1C measurement (a 4,5 ml heparin tube) will be obtained once before induction of anaesthesia. A maximum of 53mL blood loss during the study will be expected. Participation will provide no direct immediate benefit to patients. Common adverse events with liraglutide treatment are related to the gastrointestinal system, nausea as reported most frequently. Other adverse events include upper respiratory tract infections and headache. All adverse events are mostly mild and the drop-out rate from clinical trials due to adverse events has been low. The study will provide more insight in the effect of a GLP-1 receptor agonist as a glucose lowering agent in peri-operative setting and its influence on coagulation activation. This insight may help to find an optimal glycemic control strategy to diminish activation of coagulation and/or impairment of fibrinolysis and in the long run prevent VTE following hip surgery.

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

-Signed informed consent
-Planned for elective hip replacement surgery at the AMC
-Age 18-75 years inclusive
-Fraxiparine used as anticoagulant drug

Exclusion criteria

- Known type 1 or type 2 diabetes mellitus
- Oral corticosteroid use
- Use of a Vitamin K antagonist (VKA) as anticoagulant drug
- Revision hip replacement

- Known coagulation disorders
- Peripheral nerve block peri-operative
- Known active cancer of the subject
- History of chronic pancreatitis or idiopathic acute pancreatitis
- Impaired liver function, defined as alanine aminotransferase (ALAT) * 2.5 times upper normal limit
- Impaired renal function defined as serum-creatinine * 133 µmol/L for males and * 115 µmol/L for females
- 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)
- Known or suspected allergy to trial product(s) or related products
- 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
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-08-2012
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Victoza
Generic name:	Liraglutide

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26959
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-004955-38-NL
CCMO	NL38327.018.11
OMON	NL-OMON26959