Peroperative Administration of Tranexamic acid in Roux-en-Y and one-anastomosis gastric bypass to reduce hemorrhage rates (PATRY study): a randomized controlled trial

Published: 07-02-2023
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This study has been transitioned to CTIS with ID 2024-513570-22-00 check the CTIS register for the current data. This trial aims to investigate whether peroperative administration of TXA reduces haemorrhage rates in patients who undergo metabolic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON53532

Source
ToetsingOnline

Brief title
PATRY

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Gastric bypass, hemorraghe

Research involving

Human

Sponsors and support

Primary sponsor: Franciscus Ziekenhuis
Source(s) of monetary or material Support: vakgroep (bariatrische) chirurgie

Intervention

Keyword: gastic bypass, hemorrhage, metabolic surgery, Tranexamic acid

Outcome measures

Primary outcome

Primary outcome measure is postoperative reintervention (administration of packed red blood cells or, surgical-, radiological-, or endoscopic intervention).

Secondary outcome

Secondary outcome measures are the use of haemostatic staple devices and fibrin sealant preoperatively, postoperatively decrease in haemoglobin, increase in heart rate, rates of suspicions of postoperative haemorrhage (i.e. haemorrhage for which extra haemoglobin monitoring and administration of TXA) and rates of VTE, other complications, hospitalization time.

Study description

Background summary

Morbid obesity is rising, leading to an increase in metabolic surgery. Over the years postoperative venous thromboembolic events (VTE) seems to decrease, whereas the incidence of per- and postoperative haemorrhage seems to increase. Peroperative administration of tranexamic acid (TXA) may decrease the incidence of haemorrhage per- and postoperative in patients receiving metabolic surgery.

Study objective

This study has been transitioned to CTIS with ID 2024-513570-22-00 check the CTIS register for the current data.

This trial aims to investigate whether peroperative administration of TXA reduces haemorrhage rates in patients who undergo metabolic surgery.

Study design

This is a double-blind, multi-centre randomised controlled trial.

Intervention

Patients are randomised between 2 groups: 1) Single dose of 1500 mg TXA, and 2) Placebo infusion, both to be administered during induction of the procedure by anaesthesiologist.

Study burden and risks

All patients will be required to undergo one additional blood drawing in the week prior to the procedure which will be performed at their weighing appointment, meaning that this will not require an extra hospital visit. TXA has very little side effects. Therefore we conclude that the expected benefits of the intervention outweigh the minor risks involved.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria: Primary metabolic procedure; >=18 years; good command of the Dutch or English language.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: Patients unwilling to give informed consent, patients with a medical history of bleeding or VTE (defined as, pulmonary embolism (PE) or deep vein thrombosis (DVT)) and patients who use therapeutic anticoagulants. Patients will also be excluded in case of peroperative arterial bleeding or (iatrogenic) bleeding coming from surrounding organs or vascular structures such as the liver or the spleen.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-04-2023
Enrollment:	1524
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tranexamic acid
Generic name:	Cyklokapron
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-02-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-02-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EU-CTR	CTIS2024-513570-22-00
EudraCT	EUCTR2022-001384-27-NL
ClinicalTrials.gov	NCT05464394
CCMO	NL81223.100.22