

Peroperative administration of tranexamic acid in sleeve gastrectomy

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28904

Source

NTR

Brief title

PATAS

Health condition

Morbid obesity

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

peroperative use of hemostatic staples, the decrease in hemoglobin after the procedure and reoperation rates of postoperative hemorrhage

Secondary outcome

rates of deep venous thrombosis (DVT) and pulmonary embolism (PE)

Study description

Background summary

This trial aims to investigate if peroperative administration of tranexamic acid can reduce hemorrhage rates in patients undergoing a laparoscopic sleeve gastrectomy

Study objective

When administering tranexamic acid during induction of the procedure, there will be less usage of hemostatic clips. Also, postoperatively, patients will have less decrease in hemoglobin value and lesser reinterventions because of hemorrhage will be necessary.

Study design

Follow up is 3 months

Intervention

Administration of tranexamic acid versus placebo

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Primary bariatric procedure; good command of the Dutch or English language

Exclusion criteria

Patients unwilling to give informed consent, patients with a medical history of bleeding or VTE 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.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2020
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	19-04-2019

Application type:

First submission

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
NTR-new	NL8029
Other	MEC-U : R19.041

Study results