Tranexamic acid during excisional burn surgery

Published: 22-02-2021
Last updated: 25-09-2024

This study has been transitioned to CTIS with ID 2024-513573-49-00 check the CTIS register for the current data. The objectives of this study are twofold, (1) to investigate whether tranexamic acid reduces the volume of blood loss and number of...

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

Summary

ID

NL-OMON55963

Source
ToetsingOnline

Brief title
TRANEX

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
Coagulation, fibrinolysis

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Dutch Burn Foundation;Werven b.v.,Werven b.v.

Intervention

Keyword: blood loss, burns, fibrinolysis, tranexamic acid

Outcome measures

Primary outcome

The main study endpoints are the volume of blood loss and the extend of

fibrinolysis.

Secondary outcome

Blood transfusion requirements:

- Number of blood product transfused

Hospital Mortality

Length of stay

Operation success:

- Success of skin graft (percentage successful take)

Cardiopulmonary complication (i.e. arterial embolism)

Neurologic complications (i.e. stroke, conclusion)

Strength of the blood cloth and fibrin-structures

Study description

Background summary

Despite an increase in knowledge, blood loss during burn excisional surgery remains a major challenge and is an independent predictor of mortality. During burn excisional surgery limited measures are available to control the bleeding during surgery. Increased fibrinolysis could be one of the contributing factors of blood loss during burn excisional surgery. Tranexamic acid is able to inhibit the fibrinolytic response by inhibiting the conversion of plasminogen to plasmin. Indeed, a small body of evidence shows positive effects of

tranexamic acid on the volume of blood loss.

Study objective

This study has been transitioned to CTIS with ID 2024-513573-49-00 check the CTIS register for the current data.

The objectives of this study are twofold, (1) to investigate whether tranexamic acid reduces the volume of blood loss and number of allogenic transfusion, and (2) to investigate the extend of fibrinolysis during burn excisional surgery.

Study design

We will perform a multicenter double blinded randomized clinical trial in patients scheduled for burn excisional surgery within the Maasstad Hospital in Rotterdam, Rode Kruis Hospital in Bev-erwijk and Martini Hospital in Groningen.

Intervention

After induction of anesthesia, but before incision, study medication will be administered. The intervention group will receive 2000mg tranexamic acid. The placebo group will receive a NaCl 0.9% bolus.

Study burden and risks

Several large studies show that the use of tranexamic acid is safe in a diverse population. Furterhmore, current guidelines advice the use of tranexamic acid in case of large blood loss, there-fore the risk associated with participation is low. The burden on the patient is low as the inter-vention is limited to the perioperative process and blood sample can be drawn from the intrave-nous excess which part of the standard of care.

Contacts

Public
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL
Scientific
Maasstadziekenhuis

Maasstadweg 21

Rotterdam 3079DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients scheduled for burn excisional surgery
- An expected blood loss of >=250ml based on the estimation by the performing surgeon on the basis of: (1) 2 % body surface area excision planned (100-200 cc / %TBSA, based on retrospective data from Burn Centre Rotterdam), (2) operation technique used (some techniques show more blood loss than others), (3) time after burn trauma (i.e. expected healing).
- >=18 years

Exclusion criteria

- Patients with a recorded coagulopathy in their history
- Severe kidney failure (creatinine >500 umol/L)
- Allergy for tranexamic acid
- Acute venous-/arterial thrombosis (ongoing thrombosis). A history of thrombosis is NOT an exclusion criterion
- Diffuse intravascular coagulation
- Pregnancy
- History of epilepsy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2021
Enrollment:	95
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	22-02-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	09-03-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	07-06-2023

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-12-2023
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	CTIS2024-513573-49-00
EudraCT	EUCTR2020-005405-10-NL
CCMO	NL69319.100.20