Reduction of blood loss in pediatric osteotomies around the hip - A randomized placebo-controlled trial with tranexamic acid -

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This study has been transitioned to CTIS with ID 2024-516324-34-01 check the CTIS register for the current data. To evaluate (reduction of) intraoperative blood-loss with and without pre-operative TXA administration, in children undergoing a…

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON51297

Source
ToetsingOnline

Brief title
TXA-RCT

Condition

- Joint disorders

Synonym
hip dislocation, hip dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Sophiafonds;JKF fonds

Intervention

Keyword: children, osteotomy, tranexamic acid, trial

Outcome measures

Primary outcome

Primary outcome: estimated intraoperative blood loss (EBL in ml/kg, calculated with the level of suction fluids and number of soaked surgical swabs and drapes).

Secondary outcome

Secondary outcomes: baseline demographic data, indication for surgery, prior surgery at same site, treatment (type of PFPO, pelvic and/or femur, side, uni/bilateral), operative time, eventual additional antifibrinolytic agents (including TXA) administered during surgery, blood transfusions, pre- and post-operative blood values including Hb, Hct and MCV, complications, duration of hospital stay.

Study description

Background summary

Osteotomies around the hip, i.e. proximal femoral and/or pelvic osteotomies (PFPO), are major surgeries, especially for children. In general, the goal of PFPO is to prevent future hip problems in often young and asymptomatic children. Children undergoing a proximal femoral and/or pelvic osteotomy may have significant blood loss during the operation. Blood loss is associated with complications, higher mortality and longer hospital stay. Nevertheless, these interventions can be indicated in children with, e.g. hip dysplasia (DDH) or neuromuscular disorders to prevent hip dislocations, pain, loss of walking and sitting function, or osteoarthritis. Finding ways to reduce blood loss during these surgeries is therefore essential.

Tranexamic acid (TXA), an antifibrinolytic agent, is part of standard care for trauma and joint reconstruction surgery in adults as a preventive measure to minimize blood loss. TXA is registered for use in children and has been found to be safe and effective for trauma, cardiac and spinal surgery in children. However, the potential benefit for pediatric orthopedic procedures, particularly with regards to PFPO and other osteotomies, is unclear.
We have performed a retrospective study on this subject, in which we analyzed all children who had a proximal femoral and/or pelvic osteotomy in 2014-2019 at Erasmus MC-SKZ. We found a significant and clinically relevant reduction of perioperative blood loss in patients with preoperative TXA administration. However, in only 20 of the 340 studied patiens there was preoperative TXA administration. In addition, retrospective research has its limitations including, for example, confounding. Thus, although the significant reduction in blood loss found is promising, our previous study is not sufficient to implement e.g. standardized TXA use in these operations.
With this RCT we want to gain more insight in the effectiveness of TXA in pediatric orthopedic surgery, in particular PFPO. If the trial also shows that TXA reduces blood loss, this may lead to changes in protocols and guidelines, for example to apply TXA in a standardized manner in children with these osteotomies.

Study objective

This study has been transitioned to CTIS with ID 2024-516324-34-01 check the CTIS register for the current data.

To evaluate (reduction of) intraoperative blood-loss with and without pre-operative TXA administration, in children undergoing a proximal femoral and/or pelvic osteotomy (PFPO).

Study design

double-blind randomized controlled trial

Intervention

Randomisation for:
- Group A) single pre-operative intravenous bolus of TXA 15 mg/kg.
- Group B) single pre-operative intravenous bolus of placebo (no TXA).

Study burden and risks

The included subjects will undergo usual care treatment. The only study-related intervention and additional burden: randomization for either a pre-operative bolus of a placebo or a medicinal product (TXA), which is registered for use in children and currently applied in clinical paediatric orthopaedic practice on a

variable basis (physicians preference).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

The patient population is composed of all patients aged 1-18 years, undergoing a pelvic and/or femoral osteotomy (PFPO) at Erasmus MC-Sophia, for DDH, secondary hip dysplasia, or other indications.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Indication for PFPO
• Age 1-18 years

Exclusion criteria

• Contra-indication for TXA (active thromboembolic disease, subarachnoidal bleeding, severe renal insufficiency, history of convulsions, disseminated intravascular coagulation)
• Active use of alternative (anti)fibrinolytics
• Diagnosed bleeding or coagulation disorder
• Medical history of thromboembolic complications
• Insufficient Dutch Language skills of parents/care-takers
• No informed consent
• Use of hormonal contraception

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2023
Enrollment:	180
Type:	Anticipated

Medical products/devices used

Product type:	Medicine

Brand name:	Cyclokapron
Generic name:	tranexamic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-09-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-11-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	CTIS2024-516324-34-01
EudraCT	EUCTR2022-002384-30-NL
CCMO	NL81872.078.22