Tranexamic Acid to Prevent Operation in Chronic Subdural Hematoma

Published: 29-03-2018
Last updated: 09-11-2024

This study has been transitioned to CTIS with ID 2024-514927-40-02 check the CTIS register for the current data. To evaluate the efficacy of TXA to prevent surgery for cSDH

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON54811

Source
ToetsingOnline

Brief title
TORCH

Condition

- Central nervous system vascular disorders
- Nervous system, skull and spine therapeutic procedures
- Vascular haemorrhagic disorders

Synonym
brain haemorrhage, chronic haemorrhage in the subdural space

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW (ronde GGG repurposing)

Intervention

Keyword: Burr-hole surgery, Chronic Subdural Hematoma, Cost-effectiveness, Quality of Life, Tranexamic Acid

Outcome measures

Primary outcome

Necessity for surgery after 12 weeks

Secondary outcome

Functional outcome (mRS), neurological impairment (mNIHSS), performance in activities of daily living (Barthel and Lawton-Brody), cognitive functioning (MOCA), quality of life (SF-36 and EQ-5D), cSDH volume, incidence of falling, mortality rate and health care costs.

Study description

Background summary

Chronic subdural hematoma (cSDH) is a relatively frequently occurring neurological disease, occurring mainly in the elderly. Surgical evacuation of the hematoma is an effective treatment, but is also associated with life-threatening risks. In these old, often frail, patients with multi-comorbidity, surgery also comes with significant risks for future cognitive functioning and, therefore, loss of independency. In a recent large series of surgically treated patients, symptomatic recurrence was 9%, mortality 2% and unfavourable outcome 22%. Methods to prevent a surgical treatment are therefore required. In five small retrospective series, tranexamic acid (TXA), an antifibrinolytic drug, showed a beneficial effect on the spontaneous resolution of the hematoma and, with that, the necessity for surgery. This prospective study aims to prove its efficacy in a randomised and placebo-controlled trial.

Study objective

This study has been transitioned to CTIS with ID 2024-514927-40-02 check the CTIS register for the current data.

To evaluate the efficacy of TXA to prevent surgery for cSDH

Study design

Double-blind, placebo-controlled, multicentre, randomized clinical trial.

Intervention

During four weeks, the intervention group will receive oral TXA twice daily 500mg, the control group receives a placebo twice daily. The TXA or placebo treatment is additional to standard care.

Study burden and risks

Patients will use the study medication twice daily for four weeks. Follow-up is at four, eight and 12 weeks with a standard CT-scan of the head, four questionnaires and outpatient clinic visits. These outpatient clinic visits are standard care; one CT-scan, the questionnaires and extra clinical tests during the visit are extra for this study. Each patient may benefit from the study if the study medication is indeed effective in preventing surgery for cSDH. Each patient is also at risk since he or she is exposed to the potential side effects of the medication. The potential benefit, namely the prevention of a surgical treatment, outweighs the burden and risk of the temporary use of the study medication and its potential side effects as TXA is considered to be a very safe drug (e.g. the risk of thromboembolic events is only 0.01-0.1%).

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

• Age 50 years and above;
• On CT confirmed cSDH;
• Primary conservative treatment, based on clinical symptoms: Glasgow Coma Scale score >=14, mNIHSS score <=4 and a stable neurological deficit (no new, or progression of, symptoms between the assessment by the neurologist and the assessment by the neurosurgeon).

Exclusion criteria

• Primary surgical treatment based on one or more of the following symptoms or parameters: medically intractable headache, midline shift >10mm, imminent death within 24 hours;
• Structural causes for subdural haemorrhage, e.g. arachnoid cysts, cortical vascular malformations and a history of cranial surgery <1year;
• Aneurysmal subarachnoid haemorrhage;
• Active treatment for deep vein thrombosis, pulmonary embolism or cerebral thrombosis (secondary prophylaxis is not considered to be active treatment);
• Active intravascular clotting or disseminated intravascular coagulation;
• Known hypersensitivity or allergy to TXA or to any of the ingredients;
• History of a blood coagulation disorder (hypercoagulability disorder);
• History of severe impairment of renal function (eGFR <30ml/min or serum creatinine >150µmol/L);
• Amanesis with signs of anemia (fatigue, headache, exercise intolerance, weakness and pallor (conjunctival) dry skin);
• History of epilepsy;
• History of inability to safely swallow oral medication;
• Inability to obtain informed consent from the patient or legal

representative, including language barrier.

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:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-06-2018
Enrollment:	554
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	29-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	24-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	04-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-04-2023
Application type:	Amendment
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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	CTIS2024-514927-40-02
EudraCT	EUCTR2017-004311-40-NL
CCMO	NL63794.018.18