

Tranexamic acid in IntraCerebral Haemorrhage

Submission date 23/11/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/01/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/02/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

Version 1.1

Study information

Scientific Title

A randomised controlled trial of Tranexamic acid in Intracerebral Haemorrhage (TICH)

Acronym

TICH

Study objectives

Primary:

To test the feasibility, tolerability and acceptability (adverse events) of tranexamic acid in haemorrhagic stroke.

Secondary:

To test the effects of tranexamic acid on haematoma expansion and death and dependency in haemorrhagic stroke.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 2 Research Ethics Committee, 01/11/2010, ref: 10/H0308/80

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke - primary intracerebral haemorrhage

Interventions

Intravenous tranexamic acid (Cyklokapron®) or 0.9% normal saline administered as 1 g loading dose infusion over 10 minutes followed by 1 g infusion over 8 hours.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Tranexamic acid (Cyklokapron®)

Primary outcome(s)

1. Acceptability: number of patients screened that are eligible for enrolment that give informed consent
2. Tolerability: adverse events after tranexamic acid administration

Key secondary outcome(s)

Surrogate markers of efficacy:

1. Radiological: haematoma volume change on brain imaging Day 1 to Day 2
2. Haematological: full blood count (FBC) and clotting function at Day 2
3. Day 7 (or discharge from hospital) and Day 90 (end of follow-up):
 - 3.1. Dependency (modified Rankin Scale shift)
 - 3.2. Disability (change in BI)

- 3.3. Quality of life (EuroQoL)
- 3.4. Care giver burden (GHQ-28)
- 3.5. Mood (Zung depression score)
- 3.6. Cognition (MMSE)

Completion date

06/06/2012

Eligibility

Key inclusion criteria

1. Adult patients (aged over 18 years, either sex) with primary intracerebral haemorrhage confirmed on computed tomography (CT) brain scan
2. Event less than 24 hours of onset (sleep stroke - onset as bed time)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Secondary haemorrhagic stroke (anticoagulation, known vascular malformations)
2. Previous venous thrombo-embolic disease
3. Recent (within 12 months) ischaemic events (ischaemic stroke, myocardial infarction, peripheral artery disease)
4. Renal impairment (estimated glomerular filtration rate [eGFR] less than 50 mmol)
5. Pregnancy or breast feeding (pregnancy will be excluded in female patients of child bearing age with a urine pregnancy test)

Date of first enrolment

06/12/2010

Date of final enrolment

06/06/2012

Locations

Countries of recruitment

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG5 1 PB

Sponsor information

Organisation
University of Nottingham (UK)

ROR
<https://ror.org/01ee9ar58>

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)
The University of Nottingham

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Stroke Association

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No
HRA research summary			28/06/2023	No	No