Tranexamic acid in IntraCerebral Haemorrhage

Prospectively registered Submission date Recruitment status 23/11/2010 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 28/01/2011 Completed [X] Results [] Individual participant data Last Edited Condition category 24/02/2015 Circulatory System

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Drug/device/biological/vaccine name(s)

Tranexamic acid (Cyklokapron®)

Primary outcome measure

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

Secondary outcome measures

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)

Overall study start date

06/12/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24

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 [eGRF] 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)

Sponsor details

c/o Mr Paul Cartledge Research Innovation Services Kings Meadow Campus Lenton Lane Nottingham England United Kingdom NG7 2NR

Sponsor type

University/education

Website

http://www.nottingham.ac.uk

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

University/education

Funder Name

University of Nottingham (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Stroke Association

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	16	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2014		Yes	No
HRA research summary			28/06/2023	No	No