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Tranexamic acid in IntraCerebral Haemorrhage

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Phase II

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	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