ISRCTN83673558 https://doi.org/10.1186/ISRCTN83673558

Combined aspirin, clopidogrel and dipyridamole versus aspirin alone in stroke secondary prevention: a safety, tolerability and feasibility study

Submission date 26/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2005	**Overall study status** Completed	
Last Edited 08/08/2008	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Philip Bath

Contact details
Division of Stroke Medicine
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham
United Kingdom
NG5 1PB
+44 (0)115 840 4792
philip.bath@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Triple 2

Study objectives
We hypothesise that combination therapy with three antiplatelet agents that act through different mechanisms may maximise the benefit of antiplatelet treatment in the secondary prevention of stroke, both in patients with sinus rhythm and those with stroke who cannot be anticoagulated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Ischaemic stroke

Interventions
Combined aspirin (75 mg once a day [od], A), dipyridamole (200 mg twice a day [bd], B) and clopidogrel (75 mg od, C) versus aspirin (75 mg od, A) alone.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aspirin, clopidogrel, dipyridamole

Primary outcome measure
Number of subjects completing randomised treatment to final follow up.

Secondary outcome measures
1. Recurrent ischaemic stroke or TIA
2. Intracerebral haemorrhage
3. Major extracranial bleeding
4. Minor extracranial bleeding (epistaxis, purpura)
5. Sitting and standing blood pressure (BP), heart rate at 2 weeks, 3 months and follow up
6. Presence of headache

Overall study start date
26/10/2001

Completion date
28/02/2008

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Ischaemic stroke on computed tomography (CT)/magnetic resonance imaging (MRI) within 5 years
3. Previous transient ischemic attack (TIA) within 5 years
4. Written informed consent from patient
5. In sinus ryhthm or atrial fibrillation but not suitable for anticoagulation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
51

Key exclusion criteria
1. Thrombocytopenia
2. Severe hypertension
3. Previous cerebral haemorrhage
4. Hypersensitivity or intolerance to aspirin, dipyridamole or clopidogrel
5. Any history of peptic ulcer or gastrointestinal bleeding
6. Severe concomitant medical conditions including acquired immunodeficiency syndrome (AIDS) or cancer
7. Pregnancy or breast feeding
8. Patients needing or already receiving anticoagulant or non-steroidal anti-inflammatory drugs (NSAIDs) other than aspirin therapy

Date of first enrolment
26/10/2001

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Stroke Medicine
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham
England
United Kingdom

NG5 1PB
+44 (0)115 840 4791
philip.bath@nottingham.ac.uk

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

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	06/08/2008		Yes	No