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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

Registration date
28/10/2005

Overall study status
Completed

Last Edited
08/08/2008

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

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(s)
Number of subjects completing randomised treatment to final follow up.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

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

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	06/08/2008		Yes	No