

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

<b>Submission date</b> 26/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/08/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## 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 rhythm 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**

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**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?
<a href="#">Results article</a>	Results	06/08/2008		Yes	No