

The effect of allopurinol on carotid ultrasound intima-media thickness and markers of endothelial function in patients with recent stroke - a pilot study

Submission date 19/09/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/01/2009	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 27/06/2014	Condition category Circulatory System	☐ 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

Protocol serial number

TSA IMT 01

Study information

Scientific Title

The effect of allopurinol on carotid ultrasound intima-media thickness and markers of endothelial function in patients with recent stroke: a double-blind randomised placebo-controlled pilot trial

Study objectives

That allopurinol 300 mg per day will reduce rate of carotid intima-media thickness progression.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Medical Ethics Committee, approved on 19/08/2008.

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Cerebral infarction and transient ischaemic attack

Interventions

One year course of allopurinol (oral) 300 mg per day or placebo.

Details of Joint Sponsor:

University of Glasgow

University Avenue

Glasgow G12 8QQ

United Kingdom

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Allopurinol

Primary outcome(s)

Change in carotid intima-media thickness over a one year period (intima-media thickness [IMT] progression rate).

Key secondary outcome(s)

The following will be assessed at baseline, 6 and 12 months:

1. Levels of endothelial progenitor cells (EPCs) and circulating markers of endothelial function
2. Number of adverse events

Completion date

01/11/2011

Eligibility

Key inclusion criteria

1. Both males and females, aged over 18
2. Ischaemic Stroke (including transient ischaemic attack [TIA] where symptoms last less than 24 hours)
3. Brain imaging not suggestive of an alternative diagnosis
4. Randomisation within one year of ictus

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. >70% extra-cranial internal carotid artery stenosis
2. Significant co-morbidity or frailty likely to cause death within 12 months or likely to make adherence to study protocol difficult for participant
3. Contra-indication to or indication for administration of allopurinol
4. Concurrent azathioprine or 6-mercaptopurine therapy
5. Significant hepatic impairment (defined as serum bilirubin, aspartate aminotransferase [AST] or alanine aminotransferase [ALT] greater than three times upper limit of normal [ULN])
6. Estimated glomerular filtration rate <50 mls/min
7. Cognitive impairment deemed sufficient to compromise capacity to consent or to comply with the protocol
8. Women of childbearing potential
9. Prisoners

Date of first enrolment

01/11/2008

Date of final enrolment

01/11/2011

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Department of Medicine and Cardiovascular Sciences

Glasgow

United Kingdom

G11 6NT

Sponsor information

Organisation

NHS Greater Glasgow and Clyde (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (UK) (ref: TSA 2007/10)

Results and Publications

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