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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/01/2009	**Overall study status** Completed	
Last Edited 27/06/2014	**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

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.

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

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