ISRCTN11970568 https://doi.org/10.1186/ISRCTN11970568

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

Registration date
16/01/2009

Overall study status
Completed

Last Edited
27/06/2014

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/11/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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
Scotland

United Kingdom

Study participating centre
Department of Medicine and Cardiovascular Sciences
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
c/o Dr Erica Packard
Academic Research Co-ordinator
Research and Development Central Office
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Sponsor type
Government

Website
http://www.nhsgg.org.uk

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

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

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	01/07/2014		Yes	No