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Does allopurinol/urate lowering by xanthine oxidase inhibition have an impact on arterial stiffness in stroke survivors?

Submission date 29/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/12/2006	**Overall study status** Completed	
Last Edited 24/03/2011	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Res 02/ A60 2464/02/05

Study information

Scientific Title

Study objectives
After the first year of an ischaemic cerebrovascular event (stroke), cardiovascular disease becomes the most common cause of death. A growing body of evidence suggests that serum uric acid is an independent marker of cardiovascular risk. We have shown previously that high urate is associated with cardiac death in 354 stroke survivors who were followed up for a median of 2.8 years, independently of conventional risk factors for atherosclerosis, creatinine and diuretic use.

A larger study by Weir et. al., confirmed these findings and showed that higher serum urate levels, measured on admission to hospital, predicted poor outcome and higher future vascular events after acute stroke.

We sought therefore to determine how uric acid levels correlate with arterial stiffness in those who have cardiovascular disease i.e. stroke survivors. Additionally, several studies have shown that allopurinol improves endothelial function, but its effect on arterial stiffness is not known and finding this out was our second aim.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval for the study was obtained from the local ethics committee (Tayside Medical Ethics Committee, Scotland) and all subjects gave written, informed consent. All study related procedures were conducted according to institutional guidelines and the Declaration of Helsinki.

Study design
Randomised, double blinded , placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Stroke

Interventions
Patients were randomly allocated to receive either allopurinol 300 mg once daily or matched placebo. Baseline measurements were taken as part of the initial study and follow-up measurements were made after eight weeks of treatment.

Patients attended for one additional visit at two weeks, non-fasted, for measurements of urea and electrolytes, liver function testing, and for monitoring of any adverse reactions.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Allopurinol

Primary outcome measure
Correlation between arterial stiffness and urate levels.

Secondary outcome measures
Effect of allopurinol on arterial stiffness.

Overall study start date
01/02/2002

Completion date
01/04/2003

Eligibility

Key inclusion criteria
Stroke survivors who have a high serum urate

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
120

Key exclusion criteria

1. Documented reaction to allopurinol
2. Persons who were incapable of giving informed consent

Date of first enrolment
01/02/2002

Date of final enrolment
01/04/2003

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Vascular Medicine
Dundee
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Sponsor information

Organisation
University of Dundee (UK)

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Sponsor type
University/education

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ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
Chest Heart and Stroke Scotland (Grant Ref: Res 02/ A60)

Funder Name
Heart Research UK (Grant Ref 2464/02/05)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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?
Results article	results	01/11/2008		Yes	No