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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Faisel Khan

Contact details

Department of Vascular Medicine Level 7 Ninewells Hospital Dundee United Kingdom DD1 9SY +44 (0)1382 635574 f.khan@dundee.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 United Kingdom DD1 9SY

Sponsor information

Organisation

University of Dundee (UK)

Sponsor details

Nethergate
Dundee
Scotland
United Kingdom
DD1 4HN
+44 (0)1382 660111 ext 33450
j.george@dundee.ac.uk

Sponsor type

University/education

Website

http://www.dundee.ac.uk

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