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GEO 001: What is the dose-response curve between allopurinol and its effects on endothelial function in heart failure patients?

Submission date 25/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 16/12/2010	**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

242/03

Study information

Scientific Title

Acronym
GEO 001

Study objectives
High dose (600 mg) allopurinol improves endothelial function significantly more than the regular 300 mg dose

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics ref no: 242/03 (application is retrospective, trial is already complete and ethics approval was gained)

Study design
Randomised, placebo-controlled, double blind, crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Heart Failure

Interventions
Allopurinol 300 mg versus allopurinol 600 mg versus placebo

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Improvement in endothelial function

Secondary outcome measures
Urate levels and oxidative stress burden

Overall study start date
05/02/2004

Completion date
29/08/2005

Eligibility

Key inclusion criteria
1. Three-month period free of hospitalisations prior to screening

2. Ability to give written informed consent to participate in the study

3. Diagnosis of mild to moderate chronic heart failure

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. History of drug sensitivity or allergy to allopurinol or vitamin C

2. Current treatment with allopurinol , theophylline or cytotoxic drugs (including azothiaprine or mercaptopurine)

3. History of acute gout

4. Evidence of significant disease that could impair absorption, metabolism or excretion of orally administered medication i.e.

a. Renal disease (serum creatinine >160 umol/l)

b. Clinically significant hepatic disease (either by lab work, i.e. alanine aminotranferease (ALT) and aspartate aminotransferase (AST) (ALT/AST > 3 times upper limit of normal, or by clinical assessment)

5. Any condition with sufficient severity to impair co-operation in the study

6. History of chronic alcoholism / intravenous drug abuse

7. Use of another investigational drug within three months of entry into the study or within five half-lives of the investigational drug (the longer time period applying)

8. Pregnancy, breast feeding or being of childbearing age and not taking oral contraceptives

Date of first enrolment
05/02/2004

Date of final enrolment
29/08/2005

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Clinical Pharmacology
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Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovation Services
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Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation funded project PG 03/060

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	05/12/2006		Yes	No