

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/12/2010	Condition category Circulatory System	<input type="checkbox"/> 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

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 aminotransferase (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

Dundee

United Kingdom

DD1 9SY

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