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GEO 002: Is a reduction in urate levels the mechanism by which allopurinol improves endothelial function?

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 01/03/2010	**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

EudraCT number 2004-001087-51

Study information

Scientific Title

Acronym
GEO 002

Study objectives
Uric acid lowering by another mechanism (uricosuria) would elucidate whether allopurinol primarily improves endothelial function because of its ability to reduce urate effectively

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval obtained, ref no 04/S1401/66

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
Probenecid 1000 mg versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Probenecid Allopurinol

Primary outcome measure
Forearm blood flow

Secondary outcome measures
1. Oxidative stress burden
2. Urate levels

Overall study start date
02/03/2005

Completion date
15/05/2006

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 probenecid or vitamin C
2. Current treatment with probenecid, allopurinol, theophylline, warfarin or cytotoxic drugs (including azothiaprine or mercaptopurine)
3. History of acute gout or porphyria
4. Evidence of significant disease that could impair absorption, metabolism or excretion of orally-administered medication i.e.
a. Renal disease (serum creatinine 180 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, all

pre-menopausal women will be required to undergo a pregnancy test
9. Patients on aspirin doses greater than 150 mg/day

Date of first enrolment
02/03/2005

Date of final enrolment
15/05/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Deparment of Clinical Pharmacology
Dundee
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DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovation Services
University of Dundee
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Sponsor type
Research organisation

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation funded project (PG/03/060) (UK)

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