

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

<b>Submission date</b> 25/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/03/2010	<b>Condition category</b> 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 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 azothiaprime 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  $\mu\text{mol/l}$ )
  - 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, 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**

**Department of Clinical Pharmacology**

Dundee

United Kingdom

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?
<a href="#">Results article</a>	results	05/12/2006		Yes	No