

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 | <input type="checkbox"/> Prospectively registered |
| Registration date 27/01/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 01/03/2010 | Condition category Circulatory System | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacob George

Contact details
Department of Clinical Pharmacology
Level 7
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY
+44 (0)1382 660111 ext 33176
j.george@dundee.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2004-001087-51

Protocol serial number
EudraCT number

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

Primary study design

Interventional

Study design

Randomised placebo-controlled double blind crossover trial

Study type(s)

Treatment

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(s)

Forearm blood flow

Key secondary outcome(s)

1. Oxidative stress burden
2. Urate levels

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre
Department of Clinical Pharmacology
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

ROR
<https://ror.org/03h2bxq36>

Funder(s)

Funder type
Charity

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

Results and Publications

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 |