ISRCTN73579730 https://doi.org/10.1186/ISRCTN73579730

Does a drug allopurinol reduce heart muscle mass and improve blood vessel function in patients with normal blood pressure and stable angina?

Submission date 23/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/05/2009	**Overall study status** Completed	
Last Edited 29/05/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Allan Struthers

Contact details
Division of Medicine and Therapeutics
Level 7, Clinical Pharmacology Department
Ninewells Hospital and Medical School
Dundee
United Kingdom
DD1 9SY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SR001

Study information

Scientific Title
Do xanthine oxidase inhibitors reduce left ventricular hypertrophy and endothelial dysfunction in normotensive patients with chronic stable angina?: a randomised double-blind placebo-controlled single-centre trial

Study objectives
To assess if allopurinol (a drug currently used to treat gout) reduces left ventricular hypertrophy and improve endothelial dysfunction in patients with normal blood pressure and stable angina.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics A, approved on 12/02/2009 (ref: 09/S1401/3)

Study design
Randomised double-blind placebo-controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details provided in the Interventions field to request a patient information sheet.

Health condition(s) or problem(s) studied
Normotensive patients with left ventricular hypertrophy and chronic stable angina

Interventions
Patients will be given either allopurinol or placebo once a day orally. Patients will be given 100 mg for the first 2 weeks and then increased to 300 mg which is to be continued for further 4 weeks. Dosage will then be increased to 600 mg which is continue for a further 46 weeks (Total duration of interventions: 1 year).

Please use the following contact details to request a patient information sheet:
Dr Sushma Rekhraj
Clinical Research Fellow

Department of Clinical Pharmacology
Ninewells Hospital and Medical School
Dundee, DD1 9SY
United Kingdom

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
To assess left ventricular mass regression. This will be measured by cardiac MRI at baseline and then repeated after 1 year.

Secondary outcome measures
1. To assess endothelial function. This will be done by flow mediated dilatation and spygmocor. This will be performed at baseline, 6 months and then 1 year.
2. To assess if allopurinol reduces arrhythmogenicity. This will be done by looking at microvolt T wave alternans on electrocardiogram (ECG) at baseline and 1 year.

Overall study start date
07/02/2009

Completion date
06/02/2011

Eligibility

Key inclusion criteria
1. Both males and females, adults (No specific age limits)
2. Patients with blood pressure <150/90 mmHg
3. Patients with left ventricular hypertrophy
4. Patients with stable angina

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Patients with gout or already on allopurinol
2. Patients who have had a previous adverse reaction to allopurinol
3. Patients already on azathioprine
4. Patients with renal dysfunction (estimated glomerular filtration rate (eGFR) <60 ml/min)
5. Patients with heart failure or a left ventricular ejection fraction (LVEF) <45%
6. Patients who have conditions that would exclude them from undergoing an Magnetic Resonance Imaging (MRI) test such as pacemakers or any metal implants in their body
7. Patients who suffer from claustraphobia
8. Patients with cancer or lifethreatening illnesses
9. Patients who are unable to provide informed consent (e.g., learning disabilities)
10. Pregnancy or breastfeeding patients

Date of first enrolment
07/02/2009

Date of final enrolment
06/02/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Division of Medicine and Therapeutics
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
c/o James Houston
Research and Development Office
The Nethergate
Dundee
Scotland
United Kingdom
DD1 4HN

Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK) (ref: G0701592)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	05/03/2013		Yes	No

HRA research summary	28/06/2023	No	No