

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/05/2013	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

Contact name

Prof Allan Struthers

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 claustrophobia
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

