

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
Registration date 05/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/05/2013	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
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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:

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Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Allopurinol

Primary outcome(s)

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

Key secondary outcome(s)

1. To assess endothelial function. This will be done by flow mediated dilatation and spymocor. 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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Division of Medicine and Therapeutics

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

University of Dundee (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	05/03/2013		Yes	No
HRA research summary			28/06/2023	No	No