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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

Registration date
05/05/2009

Last Edited
29/05/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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United Kingdom

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 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.

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 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
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, 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes