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Do Xanthine Oxidase Inhibitors (XOI) have clinically useful anti-ischaemic effects in the treatment of angina pectoris? A double-blind, placebo controlled trial

Submission date
22/06/2007

Recruitment status
No longer recruiting

Registration date
26/06/2007

Overall study status
Completed

Last Edited
15/06/2010

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

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Additional identifiers

Protocol serial number
NOM001

Study information

Scientific Title

Study objectives
Investigating if allopurinol (a Xanthine Oxidase Inhibitor [XOI]) has anti-ischaemic effects in the treatment of chronic stable angina patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Tayside Committee on Medical Ethics in November 2006 (ref: 06/S1401/133).

Primary study design
Interventional

Study design
Double blind, placebo controlled, crossover trial.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary Artery Disease - patients with chronic stable angina

Interventions
Drug: allopurinol 300 mg - 600 mg given for six weeks.

Allopurinol (the intervention drug) is given orally (p.o.). Starting dose is 100 mg once daily (od). This is escalated over two weeks to a maximum dose of 300 mg twice daily (bd), which is given for a further period of four weeks (total six weeks). With regards to the control group, this trial is of a crossover design so each patient will be his/her own control. The placebo will be given in exactly the same fashion as the allopurinol for a total period of six weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Allopurinol (a Xanthine Oxidase Inhibitor [XOI])

Primary outcome(s)
Time to ST depression on ETT.

Outcomes will be assessed at the start and every six weeks (at the end of each treatment period - allopurinol or placebo).

Key secondary outcome(s)
1. Total exercise time
2. Time to symptom on ETT
3. Assessment of angina

4. Measurement of C-Reactive Protein (CRP), B-type Natriuretic Peptide (BNP) and Procollagen III N-terminal Peptide (PIIINP)

Outcomes will be assessed at the start and every six weeks (at the end of each treatment period - allopurinol or placebo).

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Documented Coronary artery Disease (CAD) on angiography
2. Chronic stable angina (greater than two months)
3. Able to do Exercise Treadmill Test (ETT)
4. Aged between 30 and 85 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Contra-indication or unable to do ETT
2. Already on allopurinol or previous allergy to allopurinol
3. Left Ventricular (LV) ejection fraction less than 45%
4. Myocardial Infarction (MI) or Acute Coronary Syndrome (ACS) over the last two months
5. Change to anti-anginal therapy over the last month
6. Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Graft (CABG) within the last six months
7. Significant renal or hepatic impairment
8. On medication that may interact with allopurinol (e.g., warfarin)

Date of first enrolment
22/06/2007

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Department of Clinical Pharmacology (Level 7)
Dundee
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Sponsor information

Organisation
University of Dundee (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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	19/06/2010		Yes	No