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	Recruitment status No longer recruiting	Prospectively registered		
22/06/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/06/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/06/2010	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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).

Study design

Double blind, placebo controlled, crossover trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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).

Secondary outcome measures

- 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).

Overall study start date

22/06/2007

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

Age group

Adult

Sex

Not Specified

Target number of participants

60 patients

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

Scotland

United Kingdom

Study participating centre Department of Clinical Pharmacology (Level 7)

Dundee United Kingdom DD1 9SY

Sponsor information

Organisation

University of Dundee (UK)

Sponsor details

11 Perth Road Dundee Scotland United Kingdom DD14HN

Sponsor type

University/education

Website

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

ROR

https://ror.org/03h2bxq36

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (UK)

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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	19/06/2010		Yes	No