ISRCTN96755104 https://doi.org/10.1186/ISRCTN96755104

Do xanthine oxidase inhibitors regress left ventricular hypertrophy in diabetes? A whole new approach to reducing cardiac deaths

Submission date 20/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/04/2009	**Overall study status** Completed	
Last Edited 11/07/2016	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-008485-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
eb/lm/let390/ln950/20038

Study information

Scientific Title
Do xanthine oxidase inhibitors regress left ventricular hypertrophy in diabetes? A double-blind randomised placebo-controlled trial

Study objectives
The primary aim is to see if allopurinol (a xanthine oxidase inhibitor) reduces left ventricular hypertrophy over and above normotensive type 2 diabetics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife and Forth Valley Research Ethics Committee pending approval as of 20/02/2009, ref: 09/S) 501/3

Study design
Single-centre double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Left ventricular hypertrophy

Interventions
Allpurinol or placebo will be given in a stepwise manner as shown below:
1. 100 mg/placebo once daily (od) for 2 weeks
2. 300 mg/placebo od for 2 weeks
3. 600 mg/placebo od for 1 year

Allopurinol and placebo will be given orally.

Contact details for patient information sheet:
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Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Allopurinol

Primary outcome measure
To assess if allopurinol reduces left ventricular hypertrophy in patients with diabetes

Secondary outcome measures
1. To assess if allopurinol improves endothelial function in diabetic patients will be done with flow mediated dilatation (FMD) and sphygmocor measurements. These tests will be done at time 0, 6 months and 1 year.
2. To assess if allopurinol reduces arrthymogenicity in diabetic patients will be done with a technique called microvolt T wave alternans (MTWA). This test will be done at time 0 and 1 year.

Overall study start date
02/02/2009

Completion date
01/02/2011

Eligibility

Key inclusion criteria
1. Patients with type 2 diabetes
2. Patients with left ventricular hypertrophy
3. Office target blood pressure less than 150/90 mmHg at recruitment

No age or gender restrictions.

Participant type(s)
Patient

Age group
Other

Sex

Both

Target number of participants
66

Key exclusion criteria
1. Gout
2. Already on allopurinol
3. Previous adverse reaction to allopurinol
4. Poor kidney function (estimated glomerular filtration rate [eGFR] less than 60 ml/mm)
5. Conditions that exclude magnetic resonance imaging (MRI)
6. Heart failure (left ventricular ejection fraction [LVEF] less than 45%)
7. Cancer or other life threatening illness
8. Pregnancy or breast feeding
9. Unable to provide consent

Date of first enrolment
02/02/2009

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital and Medical School
Dundee
United Kingdom
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Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research and Innovation Services
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Sponsor type
University/education

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

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK) (ref: BDA:RD08/0003627)

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

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	17/12/2013		Yes	No