

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
Registration date 20/04/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/07/2016	Condition category Circulatory System	☐ 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

Clinical Trials Information System (CTIS)
2008-008485-12

Protocol serial number
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

Primary study design

Interventional

Study design

Single-centre double-blind randomised placebo-controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 arrhythmogenicity 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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

United Kingdom

Scotland

Study participating centre

Ninewells Hospital and Medical School

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Charity

Funder Name

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

Alternative Name(s)

The British Diabetic Association, 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

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