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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

**Prof Allan Struthers** 

#### Contact details

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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

#### Study design

Single-centre double-blind randomised placebo-controlled trial

#### Primary study design

Interventional

#### 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:

Ben Szwejkowski Clinical Research Fellow Department of Clinical Pharmacology University of Dundee Ninewells Hospital and Medical School Dundee DD1 9SY United Kingdom

#### Intervention Type

Drug

#### Phase

## 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 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.

#### 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)

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