

# Do xanthine oxidase inhibitors reduce both left ventricular hypertrophy and endothelial dysfunction in cardiovascular patients with renal dysfunction?

<b>Submission date</b> 28/05/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/09/2011	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

Clinical Trials Information System (CTIS)

2007-004760-49

Protocol serial number

# Study information

## Scientific Title

### Study objectives

Patients with chronic kidney disease (CKD) mainly die from cardiovascular-related causes, with a mortality 20 times the risk of a general population. Although all the traditional risk factors are accountable, studies show that oxidative stress makes a particular contribution to the excessive cardiovascular risks. Oxidative stress promotes left ventricular hypertrophy (LVH) and causes endothelial dysfunction. LVH is known to be an independent predictor of cardiovascular events and studies have shown the survival benefits of regressing LVH. Allopurinol has been proven to be a potent antioxidant. Hence, this study looks to see if allopurinol would regress LVH and also improve endothelial dysfunction in patients with CKD.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Tayside Committee on Medical Research Ethics A. Date of approval: 05/12/2007 (ref: 07/S1401/132)

### Study design

Randomised, double-blind, placebo-controlled trial.

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Chronic kidney disease (CKD) and left ventricular hypertrophy (LVH)

### Interventions

Allopurinol 300 mg vs placebo once a day orally for 9 months

### Intervention Type

Drug

### Phase

Not Specified

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

allopurinol

### Primary outcome(s)

Reduction in left ventricular hypertrophy at 9 months

**Key secondary outcome(s)**

Reduction in endothelial dysfunction at 9 months

**Completion date**

31/10/2009

**Eligibility****Key inclusion criteria**

1. Both males and females, age >18 years old and there is no upper age limit
2. Chronic kidney disease, Stage 3 (estimated glomerular filtration rate [GFR] 30-60 ml/min)
3. Echo left ventricular hypertrophy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Known cardiac failure with left ventricular ejection fraction (LVEF) <45%
2. Patients already on allopurinol
3. Patients who have gout
4. Patients with severe hepatic disease
5. Usual contraindications to magnetic resonance imaging (MRI), including any metal implants in the body and severe claustrophobia
6. Current immunosuppressive therapy (e.g., azathioprine, ciclosporin or cyclophosphamide), chlorpropamide, theophylline or 6-mercaptopurine
7. Malignancy or other life threatening disease
8. Pregnancy and lactating women
9. Patients unable to provide informed consent (e.g., learning difficulties)

**Date of first enrolment**

15/01/2008

**Date of final enrolment**

31/10/2009

**Locations**

## Countries of recruitment

United Kingdom

Scotland

## Study participating centre

**Division of Medicine and Therapeutics**

Dundee

United Kingdom

DD1 9SY

## 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?
<a href="#">Results article</a>	results	01/07/2011		Yes	No