

# 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 <input type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/09/2011	<b>Condition category</b> Circulatory System	<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

### EudraCT/CTIS number

2007-004760-49

### IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

MK001

## **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

### **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 below to request a patient information sheet

### **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 measure**

Reduction in left ventricular hypertrophy at 9 months

**Secondary outcome measures**

Reduction in endothelial dysfunction at 9 months

**Overall study start date**

15/01/2008

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**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**

Scotland

United Kingdom

**Study participating centre****Division of Medicine and Therapeutics**

Dundee

United Kingdom

DD1 9SY

## **Sponsor information**

**Organisation**

University of Dundee (UK)

**Sponsor details**

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University of Dundee

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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**

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