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

Submission date
28/05/2008

Recruitment status
No longer recruiting

Registration date
26/06/2008

Overall study status
Completed

Last Edited
14/09/2011

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
2007-004760-49

Protocol serial number

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

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?
Results article	results	01/07/2011		Yes	No