

Effect of allopurinol on arterial stiffness indices in patients with chronic heart failure

Submission date 01/02/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/06/2018	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

Protocol serial number
201065

Study information

Scientific Title

Effect of allopurinol on arterial stiffness indices in patients with chronic heart failure: a prospective randomised double-blind placebo-controlled study

Study objectives

Allopurinol add-on therapy (300 mg daily dose for 3 months) in clinically-stable patients with chronic heart failure will result in reduction of arterial stiffness parameters, augmentation index (AIx) and aortic pulse wave velocity (PWV) (carotid-femoral).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The University of Dammam (now Imam Abdulrahman bin Faisal University) Ethics Committee, 26 /05/2010

Study design

Prospective randomised double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic heart failure

Interventions

Every patient will have a total of 4 visits.

Preliminary visit:

For explaining the nature of the trial, get the consent forms signed and for demonstration of SphygmoCardiography technique and to get the patient acclimatised to it via taking some arterial stiffness readings that will not be included in the study statistics. Blood samples will be taken for baseline screening; haematological and biochemical screening. Baseline echocardiogram and ECG will also be done.

Visit 0:

For arterial stiffness parameters measurements and baseline stress test, after which the patient will be randomised by a pharmacist to any of the treatment arms.

Safety visit:

For checking how the patient is doing with the study medication (1 month after). Blood samples will be taken for complete blood count, renal and liver function tests.

Visit 1 (3 months post-randomisation):

For arterial stiffness parameters measurements and a repeat stress test.

Medications:

Allopurinol: Apo-Allopurinol 300 mg tablet once daily (APOTEX Pharmaceutical, Canada).

Duration: 90 days.

Placebo: manufactured locally at Al Jazeera Pharmaceutical, Riyadh, Saudi Arabia, 1 tablet once daily. Duration: 90 days.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Allopurinol

Primary outcome(s)

Arterial stiffness indices:

1. Pulse wave velocity (PWV)
2. Augmentation index

Assessed at visit 0 (baseline) and after 90 days post-randomisation (visit 1)

Key secondary outcome(s)

Exercise capacity, assessed at visit 0 (baseline) and after 90 days post-randomisation (visit 1)

Completion date

01/12/2012

Eligibility

Key inclusion criteria

1. Aged greater than 18 years, either sex
2. Chronic heart failure patients with functional class II - III (according to New York Heart Association [NYHA])
3. Clinical stabilisation of cardiac condition and medications for at least 3 months prior to involvement

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Serum creatinine greater than 2 mg/dl or creatinine clearance of less than 60 ml/min
2. Recent admission to hospital within the last 3 months due to decompensated heart failure or new ischaemic event
3. Uncontrolled blood pressure (BP greater than 160/100 mmHg)
4. Concomitant antioxidant vitamins
5. Known hypersensitivity reaction to allopurinol

Date of first enrolment

08/01/2011

Date of final enrolment

01/12/2012

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Imam Abdulrahman bin Faisal University

Dammam

Saudi Arabia

31478

Sponsor information

Organisation

Imam Abdulrahman bin Faisal University

ROR

<https://ror.org/038cy8j79>

Funder(s)

Funder type

University/education

Funder Name

Imam Abdulrahman bin Faisal University

Results and Publications

Individual participant data (IPD) sharing plan

The data sets generated during and/or analyzed during the current study are/will be available upon request from Dr Manal Alem (malem@alfaisla.edu). No analyses will allowed on raw data unless agreed and approved by local ethics committee.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/06/2018		Yes	No