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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
01/02/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
01/03/2011	Completed	[X] Results
<b>Last Edited</b> 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

#### Contact name

Dr Manal Alem

### **ORCID ID**

http://orcid.org/0000-0001-8447-792X

### Contact details

Department of Pharmacology College of Medicine Imam Abdulrahman bin Faisal University PO Box 34872 Dammam Saudi Arabia 31478

malem@alfaisal.edu

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

# Secondary identifying numbers

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

# 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 to request a patient information sheet

### 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 measure

Arterial stiffness indices:

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

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

### Secondary outcome measures

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

### Overall study start date

08/01/2011

### 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

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

100

### 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

### Sponsor details

PO Box 1982 Dammam Saudi Arabia 31441

\_

dsr@ud.edu.sa

### Sponsor type

University/education

### Website

http://www.iau.edu.sa/

### **ROR**

https://ror.org/038cy8j79

# Funder(s)

# Funder type

University/education

### **Funder Name**

Imam Abdulrahman bin Faisal University

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

# 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