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

Submission date	Recruitment status	[_] Prospectively registered
01/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/06/2018	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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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