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Effect of colchicine, an anti-inflammatory drug, on the chance of developing atrial fibrillation, a fast irregular heart beat, in open heart surgery patients

Submission date
27/12/2015

Recruitment status
No longer recruiting

Registration date
31/12/2015

Overall study status
Completed

Last Edited
03/08/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One of the most common complications suffered by patients following heart (cardiac) surgery is atrial fibrillation (AF). The heart consists of two upper chambers (atria) and two lower chambers (ventricles). Inside the right atrium, a cluster of cells (sinus node) are responsible for firing electrical signals into the heart muscle causing the heart to beat regularly (sinus rhythm). When a person is suffering from AF, the normal signals from the sinus node do not work properly, causing other parts of the atria to fire chaotically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia). Colchicine is a medication which is commonly used to treat inflammation (swelling) disorders such as gout (a type of arthritis). Recent studies have shown that it could also be used to prevent people from developing AF, although further research is needed to see how effective it is. The aim of this study is to find out whether treating patients with colchicine after cardiac surgery could help to prevent AF.

Who can participate?
Adults who are having heart surgery at a participating hospital.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given 2mg colchicine 12-24 hours before their surgery and another 1mg 4 hours before their surgery through a nasogastric tube (tube in the nose which leads straight to the stomach). The participants are given 0.5mg every day until they are discharged from hospital. Those in the second group receive normal care and are not given colchicine. Participants in both groups are attached to an ECG machine (heart scanner) so that any AF can be identified. Participants in the colchicine group are also interviewed and examined every day in order to find out if they are experiencing any side effects from the medication.

What are the possible benefits and risks of participating?
Participants who receive colchicine could be protected from AF and will have a smoother

recovery period. Risks of taking part include side-effects of colchicine such as stomach upset and diarrhoea.

Where is the study run from?
Khalidi Hospital & Medical Center (lead centre) and four other hospitals in Jordan.

When is the study starting and how long is it expected to run for?
December 2012 to February 2015

Who is funding the study?
Jordan Collaborative Cardiology Group (Jordan)

Who is the main contact?
Dr Ramzi Tabbalat

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03021343

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of colchiciNe on the inciDence of Atrial Fibrillation in open heart surgery patients: The END-AF trial

Acronym
END-AF

Study objectives
The aim of this study is to determine if colchicine administered pre-operatively to patients undergoing cardiac surgery and continued during hospitalization is effective in reducing the incidence of postoperative AF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Al Khalidi Ethical Research Board (ERB),10/10/2012
2. The Istishari Hospital Internal Review Board
3. Jordan Hospital Institutional Review Board/Ethics Committee, ref: JH IRB/EC
4. Ibn Al-Haytham Hospital Ethics Committee

Study design
Prospective randomized open-label multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Atrial fibrillation post cardiac surgery

Interventions
Patients are randomized at least 12 to 24 hours prior to surgery to receive colchicine or no colchicine in an open label format. Randomization was performed by the principal investigator using an online Research Randomizer (www.randomizer.org).

Intervention group: Colchicine is administered at a dose of 2 mg 12-24 hours prior to surgery and 1 mg 4 hours before or immediately after surgery (through a nasogastric tube) and then continued at a dose of 0.5 mg twice daily until hospital discharge. Half the dose is given to patients weighing <70 kg or intolerant to the full dose
Control group: Participants receive standard care with no administration of colchicine

Partcipants in both groups are continuously monitored using ECG to find the rate of AF. Participants in the intervention group are interviewed daily to evaluate side effects from colchicine administration.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Colchicine

Primary outcome measure
1. Rate of AF is measured through continuous ECG monitoring until the time of discharge. Episodes of AF lasting for 5 minutes or more are continued significant and are recorded.
2. Occurrence of side effects is determined through daily patient examinations and patient interviews until the time of discharge

Secondary outcome measures
None

Overall study start date
16/10/2012

Completion date
03/02/2015

Eligibility

Key inclusion criteria
All adult patients undergoing elective cardiac surgery and cared for by participating cardiologists.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360

Total final enrolment
360

Key exclusion criteria

1. Patients with a documented history of AF or supraventricular arrhythmia or, with absence of sinus rhythm on hospital admission
2. Known severe liver disease or current transaminases >1.5 times the upper normal limit
3. Current serum creatinine >2.5 mg/dl
4. Known myopathy or elevated baseline preoperative creatine kinase
5. Known blood dyscrasias
6. Significant gastrointestinal disease
7. Pregnant and lactating women
8. Known hypersensitivity to colchicine
9. Current treatment with colchicine for any indications
10. Emergency surgery

Date of first enrolment
16/10/2012

Date of final enrolment
26/01/2015

Locations

Countries of recruitment
Jordan

Study participating centre
Khalidi Hospital and Medical Center
Amman
Jordan
11183

Study participating centre
Istishari Hospital
Amman
Jordan
11183

Study participating centre
Jordan Hospital
Amman
Jordan
1183

Study participating centre

Islami Hospital
Amman
Jordan
11165

Study participating centre
Ibn Haytham Hospital
Amman
Jordan
11181

Sponsor information

Organisation
Jordan Collaborative Cardiology Group

Sponsor details
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Jordan Collaborative Cardiology Group

Results and Publications

Publication and dissemination plan

The results were presented as an abstract in the ESC meeting in London, 2015. The manuscript is to be submitted to the International Journal of Cardiology for publication.

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016	29/01/2019	Yes	No