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The efficacy and safety of prednisolone in the prevention of re-accumulation of ascites among endomyocardial fibrosis (EMF) patients at Mulago hospital

Submission date
20/02/2012

Recruitment status
No longer recruiting

Registration date
28/03/2013

Overall study status
Completed

Last Edited
17/12/2015

Condition category
Circulatory System

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

Plain English summary of protocol
Background and study aims
Endomyocardial fibrosis is a restrictive cardiomyopathy (heart muscle disease) of unknown origin and is thought to be the most common type of restrictive cardiomyopathy worldwide. Ongoing inflammation and fibrosis in the heart and other parts of the body like the peritoneum may explain the exudative ascites (accumulation of fluid) found in these patients. Ascites is the commonest presentation of these patients in Uganda and is a source of acute discomfort and pain. Medical treatment for this ascites is disappointing. We would therefore like to study if predinisolone, an anti-inflammatory agent, can prevent re-accumulation of ascites if a patient is tapped from grade 3 or more to grade 2 in two months.
The aim of this study is to determine the efficacy and safety of prednisolone when used in preventing re-accumulation of ascites among EMF patients. This will specifically be done by determining the efficacy of prednisolone in preventing re-accumulation of ascites from grade 2 to grade 3 or more among EMF patients attending Mulago hospital cardiology service. Secondly, describe the adverse effects of prednisolone when used in preventing re-accumulation of ascites among EMF patients attending Mulago cardiology service.

Who can participate?
Patients with a diagnosis of EMF and have ascites, both sexes, 13years and older who have consented to participate in the trial. Patients will be excluded if they are found to be critically ill with unstable vital parameters, are using steroids within the previous month for any other indication or if they are found to be pregnant.

What does the study involve?
Participants are randomly allocated to receive either Oral prednisolone 1mg/kg or placebo (dummy), given once a day in the morning for two months then tapered for one month.

What are the possible benefits and risks of participating?
Subjects will receive free trial medication and check-ups throughout the duration that they will

be in the study. If the study finds that the drugs being tested are effective in reducing ascites due to EMF, the information generated will help to improve the treatment, and hopefully, the quality of life of many people suffering from Endomyocardial fibrosis with debilitating ascites. They will have contributed significantly for the benefit of many more people who might be having Endomyocardial fibrosis in this country and many other parts of the World. All procedures of this study involve no more than minimal risk to you as a participant. Paracentesis (form of body fluid sampling procedure) will be done by an experienced doctor. You might experience pain on the site of the injection or site of blood draw for a short period. There is also a small chance that steroids could increase the risk of infection. Very rarely prednisone can cause high blood pressure and diabetes. You will be monitored for these side effects and, the treatment will be stopped if necessary. Fortunately these side effects do disappear when prednisolone is stopped. Pregnant women will however be excluded to protect the foetus and contraception will be advised among those who will be included in the study. Overall the benefits will outweigh the risks.

Where is the study run from?
Mulago hospital cardiology service (Mulago hospital ward 4C cardiology, Cardiology clinic and Uganda heart institute Mulago.

When is the study starting and how long is it expected to run for?
April 2012 to August 2012

Who is funding the study?
Makerere University College of Health Sciences, Uganda - MEPI-CVD Linked project

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001 Version 1

Study information

Scientific Title
The efficacy and safety of prednisolone in the prevention of re-accumulation of ascites among endomyocardial fibrosis (EMF) patients at Mulago hospital: a randomised clinical trial

Acronym
PREF

Study objectives
Giving oral prednisolone at 1mg/kg per day to EMF patients with grade 2 ascites will prevent 35% of these patients re-accumulating to grade 3 ascites or more.

Null hypothesis: Giving oral prednisolone at 1mg/kg per day to EMF patients with grade 2 ascites will not prevent 35% of these patients re-accumulating to grade 3 ascites or more.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Makerere University College of Health Sciences School of Medicine, 23/12/2011, REC ref: 2011-252

Study design
Randomised placebo-controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Endomyocardial fibrosis

Interventions
1. Oral prednisolone 1mg/kg
2. Placebo 1mg/kg
Given once a day in the morning for two months then tapered for one month.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Variables to determine efficacy will include proportion of patients receiving prednisolone prevented from re- accumulating ascites from grade 2 to grade 3 at the end of two months of treatment.
2. Time to re-accumulation of ascites from grade 2 to grade 3 (requirement for paracentesis)
3. Cummulative increase in abdominal girth from baseline until requirement for paracentesis

Secondary outcome measures
Variables to determine the safety profile of prednisolone when given to these patients will be measured a questionnaire containing questions on particular side effects as well as physical examination and investigations will be used to determine these side effects and grade them as mild moderate and severe.

Overall study start date
01/03/2012

Completion date
01/08/2012

Eligibility

Key inclusion criteria
1. Age: 13 years and older, either sex
2. Patients with a diagnosis of endomyocardial fibrosis and ascites
3. For patients already on corticosteroids a wash out period of 1month will be allowed before recruitment into the trial
4. Consent/ assent to participate in the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Critically ill patients with unstable vital parameters
2. Use of corticosteroids within the previous month for other indications
3. Pregnancy

Date of first enrolment
01/03/2012

Date of final enrolment
01/08/2012

Locations

Countries of recruitment
Uganda

Study participating centre
P.O. Box 23543
Kampala
Uganda
256

Sponsor information

Organisation
Makerere University College of Health Sciences (Uganda)

Sponsor details
P.O.Box 7072
Kampala
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256

Sponsor type
University/education

Website
http://chs.mak.ac.ug/

ROR
https://ror.org/03dmz0111

Funder(s)

Funder type
University/education

Funder Name
Makerere University College of Health Sciences (Uganda) - MEPI-CVD Linked project

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	15/12/2015		Yes	No