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Preservation of renal function in cardiac surgery patients with low cardiac output syndrome: levosimendan vs beta agonists

Submission date 28/06/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/10/2019	**Overall study status** Completed	
Last Edited 19/11/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Research has been conducted to assess the effects of the drug levosimendan on heart function when given to patients with low cardiac output syndrome (LCOS) in the period immediately after heart surgery. Postoperative kidney failure is an independent predictor of mortality. Levosimendan is used for LCOS and – apart from its cardioprotective effects – seems to have a protective role on kidney function. The aim of this study is to find out whether the use of levosimendan as compared to beta-agonists in heart surgery patients with LCOS and kidney failure has beneficial effects on kidney function that are independent from its cardioprotective effects.

Who can participate?
Patients with low cardiac output syndrome (LCOS)

What does the study involve?
Participants are treated with either beta-agonists or levosimendan. The incidence of postoperative kidney failure is assessed.

What are the possible benefits and risks of participating?
These are the same as usual treatment.

Where is the study run from?
HU Virgen de la Victoria (Spain)

When is the study starting and how long is it expected to run for?
January 2015 to May 2018

Who is funding the study?
FIMABIS (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CEIMAN-26-2-14/BGC

Study information

Scientific Title
Preservation of renal function in cardiac surgery patients with low cardiac output syndrome: levosimendan vs beta agonists

Acronym
CEIMAN-26-2-14/BGC

Study objectives
It is postulated that the use of levosimendan as compared to beta-agonists in cardiac surgery patients with LCOS and kidney failure exerts beneficial preconditioning effects on renal function that are independent from its cardioprotective effects.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 27/02/2014, CEI Malaga Norte (Hospital Regional Universitario, 7ª planta Pabellón A, Avda. –Carlos Haya s/n, 29010-Málaga, Spain; Tel: +34 (0)951 29 1447/+34 (0)951 29 1977), no reference numbers attached

Study design
Quasi-experiment study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Low cardiac output syndrome (LCOS)

Interventions
It was a quasi-experiment study used to estimate the causal impact of an intervention on the target population without random assignment. Quasi-experimental research shares similarities with the traditional experimental design or randomized controlled trial, but it specifically lacks the element of random assignment to treatment or control. As it was a quasi-experimental study, recruitment was maintained until 50 patients were reached in each of the groups.

Patients were divided into two groups based on the therapy received, namely beta-agonists vs levosimendan. The administration of beta-agonists was maintained until LCOS resolution, whereas levosimendan was administered for 24 h at a rate of 0.1 mcg/kg/min at a target dose of 12.5 mg. The objectives of the therapy included a CI >2 l/min/m2 with a central venous saturation > 65% following volume replacement. Data were collected during the preoperative (heart and renal function data prior to surgery) and intraoperative period, at diagnosis of LCOS, at 24 h and at 48 h after diagnosis (24 h following completion of levosimendan therapy) and at discharge from the ICU.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levosimendan, beta agonists

Primary outcome measure
Renal function parameters:
1. Creatinine measured using ELISA at baseline, 24 and 48 hours and ICU discharge
2. Stage of renal failure measured by the Acute renal failure (AKI) scale at baseline, 24 and 48 hours and ICU discharge
3. Diuresis and use of diuretics (mg of furosemide) measured using diuresis output at baseline, 24 and 48 hours and ICU discharge
4. Requirement of renal replacement therapy measured using dialysis therapy at ICU discharge

Secondary outcome measures
Hemodynamics:
1. HR (arrhythmia de novo) measured using EKG at baseline, 24 and 48 hours and ICU discharge
2. Multifocal atrial tachycardia (MAT) measured using EKG at baseline, 24 and 48 hours and ICU discharge
3. Heart failure (HF) measured using locs definition at baseline, 24 and 48 hours and ICU discharge
4. Ejection fraction of the left ventricle (EFLV) measured using Echo at baseline, 24 and 48 hours and ICU discharge
5. SvcO2 measured using oximetry at baseline, 24 and 48 hours and ICU discharge
6. Central venous pressure (CVP) measured using pressure transductor at baseline, 24 and 48 hours and ICU discharge

Overall study start date
01/01/2015

Completion date
01/05/2018

Eligibility

Key inclusion criteria
1. Patients older than 18 years who developed postoperative low cardiac output syndrome (LCOS) following heart surgery
2. LCOS (was defined as: a cardiac index < 2l/min/m2, or central venous saturation <65% after volume replacement) . It was checked by echocardiogram and Mostcare® (continuous cardiac index monitoring)
3. Patients who required inotropic support for the treatment of LCOS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Patients who required combined surgery (not only cardiac surgery)
2. Emergency surgery
3. Preoperative diagnosis of chronic kidney failure

Date of first enrolment
01/02/2015

Date of final enrolment
01/05/2018

Locations

Countries of recruitment
Spain

Study participating centre
Hu Virgen De La Victoria
Campus Teatinos SN
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Sponsor information

Organisation
FIMABIS

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/002nw1r81

Funder(s)

Funder type
Research organisation

Funder Name
FIMABIS

Results and Publications

Publication and dissemination plan
Planned publication in BMC Anesthesiology.

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/11/2019	19/11/2019	Yes	No