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Comparison of Levosimendan and Dobutamine in cardiac surgery

Submission date	Recruitment status	[ ] Prospectively registered
16/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/05/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/04/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During heart (cardiac) surgery there are varying degrees of short-lived damage to heart tissure. Many protective strategies have been used to decrease this injury and improve strength of cardiac contraction (contractility). Levosimendan is a medication that has anti-ischaemic effects, which means it helps improve blood flow and therefore oxygen supply, and improves myocardial contractility. These properties suggest potential advantages in high – risk cardiac valve surgery patients where cardioprotection would be valuable.

Who can participate?
Adults aged over 18 years undergoing surgery for heart failure

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the drug Levosimendan during the procedure.
Those in the second group receive a different drug called Dobutamine.
All participants have general anaesthesia and undergo blood flow monitoring throughout.

What are the possible benefits and risks of participating?
Participants may benefit from hemodynamic stability during and after surgery. They also help us identify the benefits for other patients.

Where is the study run from?
National Medical Center 'La Raza' (Mexico)

When is the study starting and how long is it expected to run for?
January 2016 to January 2018

Who is funding the study?
National Medical Center 'La Raza' (Mexico)

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R-2017-1302-17

Study information

Scientific Title
Hemodynamic effects of Levosimendan in patient undergoing off–pump coronary artery bypass grafting and mitral valve replacement

Study objectives
The use of Levosimendan, in patients undergoing off–pump coronary artery bypass grafting and mitral valve replacement has hemodynamic stability compared to Dobutamine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and Research Committee of Medical National Center “La Raza”, 14/02/2017, ref: 13 CI 14 039 254 COFEPRIS

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Heart failure

Interventions
Participants are randomly allocated to group A (intervention) who receive Levosimendan (SIMDAX ®, country of origin Finland) 0.1mg/kg/min during the transanesthetic, postanesthetic and intensive therapy unit.
Those in group B (control) receive Dobutamine 3-8mg/kg/min infusion.
All participants undergo standardised balanced general anaesthesia and invasive monitoring for the measurement of hemodynamic parameters.
At the end of the surgical procedure, the patients are transferred to the Intensive Care Unit.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Heart failure is recorded if CI <2.0 L/minm2 up to 48 hours postoperatively.
2. Low cardiac output defined 2 L/min/m2. Cardiac index is calculated from cardiac output, which is measured using the thermodilution technique via the Swan-Ganz catheter up to 48 hours postoperatively.

Secondary outcome measures
1. Central venous pressure, pulmonary capillary wedge pressure, systemic vascular resistance are measured with a pulmonary artery catheter.
2. Arterial blood pressure is measured via an arterial catheter.
3. Mixed venous oxygen saturation (SV02) is measured by analysis of blood gases.

All the above outcomes are assessed on arrival back in the ICU following surgery (T1) and 48 hours postoperatively (T2).

Overall study start date
21/01/2016

Completion date
21/01/2018

Eligibility

Key inclusion criteria
1. Adult patients aged over 18 years
2. Left ventricular ejection fraction ≥=30%.
3. NYHA III-IV.
4. IC ≤ 2.5L
5. ASA II or ASA III

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
None

Date of first enrolment
01/08/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Mexico

Study participating centre
National Medical Center 'La Raza'
Calzada Vallejo Y Paseo de Las Jacarandas S/N
La Raza
02990 Ciudad de México

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Mexico
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Sponsor information

Organisation
National Medical Center 'La Raza'

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/004vn8r55

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Medical Center 'La Raza'

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan

Data is stored at the following address by the responsible researchers: http://sirelcis.imss.gob.mx/

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	14/05/2018	01/04/2019	No	Yes