

Comparison of Levosimendan and Dobutamine in cardiac surgery

Submission date 16/04/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/05/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/04/2019	Condition category Circulatory System	☐ Individual participant data ☐ 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 tissue. 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled clinical trial

Study type(s)

Treatment

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(s)

1. Heart failure is recorded if CI < 2.0 L/min/m² 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.

Key secondary outcome(s)

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).

Completion date

21/01/2018

Eligibility**Key inclusion criteria**

1. Adult patients aged over 18 years
2. Left ventricular ejection fraction $\geq 30\%$.
3. NYHA III-IV.
4. IC ≤ 2.5 L
5. ASA II or ASA III

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Mexico City

Mexico

02990

Sponsor information**Organisation**

National Medical Center 'La Raza'

ROR

<https://ror.org/004vn8r55>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

National Medical Center 'La Raza'

Results and Publications

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