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Can a drug that improves blood flow and oxygen supply to the heart improve outcomes during and after heart surgery?

Submission date
13/12/2018

Recruitment status
No longer recruiting

Registration date
24/06/2019

Overall study status
Completed

Last Edited
17/01/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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). Dexmedetomidine 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 Dexmedetomidine during the procedure. Those in the second group receive a different drug called Esmolol. 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?
General Hospital "Doctor Gaudencio González Garza" of the National Medical Center La Raza (Mexico)

When is the study starting and how long is it expected to run for?
January 2014 to May 2017

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

Who is the main contact?
Dr. Nayely Garcia Mendez (Ph Scientific) ayeyigm@yahoo.com.mx
Dr. Guillermo Careaga (Ph Scientific) gcareaga3@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Nayely García-Méndez

ORCID ID
http://orcid.org/0000-0002-2251-8148

Contact details
Oriente 158. No. 147 Col Moctezuma 2da. sección. CP. 15530 Delegación Venustiano Carranza. México. Ciudad de México
Ciudad de México
Mexico
15530
946431070
ayeyigm@yahoo.com.mx

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R-2013-3502-48

Study information

Scientific Title
Esmolol vs dexmedetomidine for attenuation of haemodynamic responses in patients undergoing elective off-pump coronary artery bypass grafting: a randomised controlled trial

Acronym
N/A

Study objectives
The use of dexmedetomidine in patient undergoing off pump coronary artery bypass grafting they present with haemodynamic stability in comparison with esmolol

Ethics approval required

Old ethics approval format

Ethics approval(s)
Hospital ethics committee on Medical Center "La Raza" (Comité Local de Investigación y Ética en Investigación en Salud), 14/12/2013, ref. 3502

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
No participant information sheet available

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

Interventions
A controlled clinical study in patients undergoing elective coronary revascularization during off pump coronary artery bypass grafting, under standardized general anesthesia. Randomly received infusions of Esmolol 0.5 mg /kg/1 min (Group E, n=10) or Dexmedetomidine 0.5 cg/kg /hr. (Group DEX, n=10). Randomization was carried out through a random number generator, by means of repetitions divided into 2 treatments, with The R Foundation for Statistical Computing Version 2.15.1 package. The monitored parameters were: invasive blood pressure, oxygen saturation, electrocardiogram, bispectral index for the depth of anesthesia, and central catheter. The hemodynamic data outcome variables of study : heart rate and invasive blood pressure were analyzed at different times: t1) basal, t2) sternotomy, t3) coronary artery bypass and t4) sternal wires during surgery. We have compared analysis of hemodynamic profile, narcotics and muscle relaxant rate, arterial blood gas and fluid were recorded during surgery. All patients underwent balanced general anesthesia with desflurane and invasive monitoring for the measurement of hemodynamic parameters. At the end of the surgical procedure, the patients were transferred to the Intensive Care Unit (ICU).

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 will be assessed using a pulmonary artery catheter at were stratified by quartiles of mean CVP during the first 48 hours after ICU admission.
2. Pulmonary capillary wedge pressure will be assessed using a pulmonary artery catheter. The changes in the pulmonary circulation in 20 cardiac surgery patients undergoing off pump coronary artery bypass grafting.
3. Low systemic vascular resistance during cardiac surgery will be assessed using a pulmonary artery catheter, and vigileo monitor for data outcome variables.
4. Diference in perioperative arterial blood preassure measered by Arterial blood pressure will be assessed using an arterial radial catheter during the first 48 h after ICU admission.
5. Mixed venous oxygen saturation (SVO2) will be assessed by analysis of blood gases by vigileo monitor.
6. Variables of haemodynamics monitoring by Vigileo Monitor EDWARDS LIFESCIENCES, in cardiac surgery patients undergoing off pump coronary artery bypass grafting, moniroring cardiac output, surgical patients requiring continuous invasive monitoring during ICU stay. Start in induction of anaesthesia, sternotomy, grafting of coronary descending, post-revascularization and 48 h after ICU.
7. Laboratory results related to organ dysfunction and the length of ICU admission and hospitalization.

Overall study start date
01/01/2014

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Off-pump cardiac surgery
3. Left ventricular ejection fraction ≥40%
4. New York Heart Association classification III-IV
4. IC ≤2.5 L
5. American Society of Anaesthesiologists (ASA) physical status classification II or III

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Patients with liver or kidney failure.
2. Patients requiring coronary revascularization with extracorporeal circulation.
3. Candidates for cardiac reoperation.
4. Patients with hemodynamic instability, cardiogenic shock.

Date of first enrolment
01/03/2014

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
Mexico

Study participating centre
General Hospital "Doctor Gaudencio González Garza" of the National Medical Center La Raza
National Medical Center 'La Raza'
Calzada Vallejo Y Paseo de Las Jacarandas S/N La Raza
Mexico City
Mexico
02990

Sponsor information

Organisation
UNIVERSIDAD LA FRONTERA

Sponsor details
Facultad de Medicina - UFRO
Manuel Montt 112 -Of.408 4º piso
Temuco
Tel. 45-25-96-917, ext. 6917
Temuco, Chile
Chile
4780000
45-25-96-917, ext. 6917
tamara.otzen@ufrontera.cl

Sponsor type
University/education

Website
https://www.ufro.cl

Organisation
UNIVERSIDAD NACIONAL AUTÓNOMA DE MÉXICO

Sponsor details
University City
Coyoacán
Mexico City
Mexico
04510
-
abc@email.com

Sponsor type
University/education

Website
www.unam.mx

Organisation
University of La Frontera

Sponsor details

Sponsor type
Not defined

Website
http://www.ufro.cl/

ROR
https://ror.org/04v0snf24

Funder(s)

Funder type
Government

Funder Name
INSTITUTO MEXICANO DEL SEGURO SOCIAL

Results and Publications

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

Intention to publish date
30/12/2018

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