ISRCTN14974395 https://doi.org/10.1186/ISRCTN14974395

The effect of non-steroidal anti-inflammatory drugs on bleeding, platelet function and consumption of opiates following cardiac surgery

Submission date
07/04/2018

Recruitment status
No longer recruiting

Registration date
25/04/2018

Overall study status
Completed

Last Edited
30/03/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
The pain following heart surgery is mostly associated with sternotomy (surgical procedure to divide the sternum), pericardiectomy (removal of the membrane around the heart), chest tube insertion, and the removal of a vein from a patient's leg. Traditionally, intravenous opioids are used for pain management after heart surgery.
However, their use is associated with side effects, such as nausea, vomiting, itching, urinary retention, intestinal paresis, and respiratory depression. Long-acting opioids administered after surgery postpone the removal of the ventilation tube in the windpipe (extubation) due to increased sedation and respiratory depression (inadequate slow and shallow breathing).
A combination of nonsteroidal anti-inflammatory drugs (NSAID) and opioid analgetics has been recommended for pain relief after major surgeries. The need of opioid analgesics can be reduced by using NSAIDs, thus also reducing the side effects of opioid analgesics, especially nausea and vomiting. The combination of NSAID and opioid analgesics contributes to an earlier extubation and patient mobilisation leading to an early discarge from the ICU.
The aim of the study is to confirm whether NSAID diclofenac decreases the use of opioid analgesics following cardiac surgery during the first 20 hours after surgery.

Who can participate?
Adults aged 20 – 85 years undergoing elective cardiac surgery

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive intravenous Diclofenac after cardiac surgery, whilst those in the control group receive intravenous saline. Participants are followed up for 20 hours after surgery.

What are the possible benefits and risks of participating?
There are no specific benefits or risks for those taking part in the study.

Where is the study run from?
University Medical Centre Maribor (Slovenia)

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

Who is funding the study?
University Medical Centre Maribor (Slovenia)

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
0120-430/2016-2

Study information

Scientific Title
The effect of diclofenac on bleeding, platelet function, and the use of opiates following coronary artery bypass graft

Study objectives
The purpose of the study is to establish whether using diclofenac after a coronary artery bypass graft (CABG) with extracorporeal circuit decreases the consumption of opioid analgesics and

their side effects. It also aims to establish whether diclofenac disrupts the platelet function and consequently increases bleeding and transfusion of blood and blood products after cardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Commission of the Republic of Slovenia for Medical Ethics (Komisija Republike Slovenije za medicinsko etiko), 22/08/16, ref: 0120-430
2. Republic of Slovenia National Medical Ethics Committee (NMEC) 10/08/2016, ref: 2016-2

Study design
Single-centre prospective randomised controlled study

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
Cardiac surgery

Interventions
After cardiac surgery, participants are randomised to one of two treatment groups using coin randomisation.
1. The treatment group receive an intravenous infusion of 75 mg diclofenac (250 ml Neodolpasse) within 90 minutes to three hours after cardiac surgery, and again after 12 hours.
2. The control group receive an infusion of 250 ml of saline (0.9% NaCl) within 90 minutes to three hours after surgery, and again after 12 hours.

Both groups are followed up 20 hours after surgery.
Both groups receive intravenous bolus piritramid 0.05 mg/kg body weight every six hours for postoperative pain relief. In addition to basal pain relief the patients receive additional piritramid 0.025 mg/kg on request by means of nurse controlled analgesia to achieve adequate analgesia (NRS ≤ 3).

Intervention Type
Drug

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

Primary outcome measure
1. Pain is measured using the NRS (numerical rating scale) for pain assessment at 1 hour intervals until 20 hours after surgery
2. The use of piritramide is recorded within the first 20 hours after surgery
3. The use of blood and blood product is recorded within the first 20 hours after surgery

Secondary outcome measures
1. Heamodynamic data (invasive blood pressure and heart rate) is measured using Phillips MX 800 monitor at 1 hour intervals until 20 hours after surgery
2. Sternal drain blood loss is measured using Sternal drainage system Atrium at 1 hour intervals until 20 hours after surgery
3. Time to extubation and time of ICU stay is recorded.
4. Unfavourable side effects are recorded during the ICU stay

Overall study start date
01/05/2016

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Adult aged 20 - 85 years
2. Operated for elective cardiac surgery using extracorporeal circuit

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
72

Key exclusion criteria
1. History of peptic ulcer disease, gastointestinal bleeding
2. Renal and liver insufficiency
3. Allergy for nonsteroidal analgetics

4. Increased bleeding during surgery
5. Increased bleeding after surgery, as defined by the chest tube drainage of more than 300 ml per hour during the first 3 hours after surgery.

Date of first enrolment
30/10/2016

Date of final enrolment
30/08/2018

Locations

Countries of recruitment
Slovenia

Study participating centre
University Medical Centre Maribor
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Maribor

Results and Publications

Publication and dissemination plan
Planned publication of results in Medical Journals.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

Additional documents are available upon request from the author.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/11/2019	30/03/2020	Yes	No