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Testing a novel, self-contained chest drainage system (THOPAZ+) for post-operative cardiac drainage

Submission date
29/05/2019

Recruitment status
No longer recruiting

Registration date
07/06/2019

Overall study status
Completed

Last Edited
27/08/2019

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Most cardiac procedures still require the use of cardiopulmonary bypass (CPB) and a sternotomy. One of the complications after such procedures is bleeding, since patients have to be fully anti-coagulated during CPB and therefore require post-operative chest drainage.
Aim: A new, self-contained, electronic, continuous pump-driven chest drainage system is compared for the first time in an RCT to a traditional wall-suction system in cardiac surgery.

Who can participate?
Adult elective cardiac patients undergoing CABG and/or valve surgery.

What does the study involve?
Patients undergoing cardiac surgery require post-operative chest-drainage in order to evacuate blood and clot formation. This is achieved with one or several chest-tubes which are hooked to a conventional canister system drained by vacuum. The aim of our study was to assess a new, self-contained, battery-operated, digital drainage system (THOPAZ+) and to compare it to a conventional system. Our prospective, randomized clinical trial included 120 patients undergoing elective routine cardiac surgery. They were randomized between the group with conventional and the group with THOPAZ+ drainage.

What are the possible benefits and risks of participating?
The benefits of the new system are a continuous drainage from the operating room until the chest-tube removal, the possibility to mobilize the patient and the presence of alarms on the THOPAZ+ system and a shorter drainage duration which may have a positive impact on the outcome of the patient.

Where is the study run from?
Department of Cardiac Surgery, University Hospital, Verona, Italy.

When is the study starting and how long is it expected to run for?
September 2015 to June 2016

Who is funding the study?
Medela AG, Switzerland

Who is the main contact?
Dr Luca Barozzi,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
584CESC

Study information

Scientific Title
Randomized controlled trial of a novel, self-contained chest drainage system in cardiac surgery

Acronym
ThopCard2

Study objectives
Improvement of chest drainage: we have investigated a new chest drainage system THOPAZ+ (Medela AG, Switzerland) to improve and simplify the management of chest drainage after cardiac surgical procedures and which gives the patient a small, mobile, user-friendly, continuous suction from the operating table to the ICU/ward.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/07/2015, Ethics Committee of the University of Verona (Borgo Trento, P. le A. Stefani, 1-37126 Verona, Italy; 045 8123236; comitatoetico.veronarovigo@ospedaleuniverona.it), ref: 584CESC.

Study design
Interventional single centre 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
This study compared the conventional chest drainage system (Argyle Aqua-Seal, Covidien, USA) with the new THOPAZ+ digital self-contained system from the end of cardiac surgery until the chest tube removal.

Randomization: Patients were allocated to either the usual suction system or the Thopaz+ pump using block randomization, with blocks of 4 or 6 (block size is also random). Group allocation was put in sealed envelopes, which were opened after surgery, just before the OR nurse opened the tubing system. Thus, the surgical team was blinded to the suction system during the surgery.

All the data were collected prospectively during the study by two surgical residents and supervised by Dr. Luca Barozzi.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Adequecy of chest drainage with THOPAZ+ measured on the digital read-out of the THOPAZ+ (in ml of drainage fluid) at the following time points: end of OR, before and after transport to ICU, on ICU (hourly), POD1, and at chest-tube removal.

Secondary outcome measures
Patient safety and Satisfaction Assessment of the hospital personnel.
1. The patient safety was part of the routine ICU care of the patient and special attention was given to the functioning of the THOPAZ+ chest drainage system, e.g. fluid collection, air leak.
2. The satisfaction assessment of the hospital personnel was performed with a short, internet-based form was filled by the users according to their specialty, e.g. cardiac surgeons, anesthetists, nurses to measure the following characteristics of the device on a visual analog scale (from 0 to 10).
-Ease of use
-No/reduced milking
-Mobility of patients
-Noise reduction
-Gain of time
-Security for patients
-How useful were the alarms?

Overall study start date
24/09/2014

Completion date
20/06/2016

Eligibility

Key inclusion criteria
1. Adult aged 18 - 80 years
2. Scheduled to undergo elective, first-time: CABG, valve surgeries and combinations with cardio-pulmonary bypass (CPB)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 patients were randomized for the two drainage systems.

Key exclusion criteria
1. Unstable angina
2. Emergency procedures
3. Off-pump surgery
4. Re-operation
5. Anti-coagulation or anti-platelet therapy (except aspirin cardio) until surgery

Date of first enrolment
17/09/2015

Date of final enrolment
14/06/2016

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
Medela AG

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Sponsor type
Industry

ROR
https://ror.org/02cedh792

Funder(s)

Funder type
Industry

Funder Name
Medela AG

Results and Publications

Publication and dissemination plan
BMC Critical Care

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on special request from Dr. Luca Barozzi, luca.barozzi@ospedaleuniverona.it with the following access criteria: detailed description for which purpose the anonymized data, or part of the data, will be used and only after having received permission from the Ethical Commission of the University of Verona.

IPD sharing plan summary
Data sharing statement to be made available at a later date