ISRCTN71768341 https://doi.org/10.1186/ISRCTN71768341

Treatment of patients undergoing cardiac surgery in a Fast-Track-Protocol in specialized anesthetic care unit compared to treatment in a Fast-Track-Protocol on ICU

Submission date
24/02/2014

Registration date
11/03/2014

Last Edited
21/08/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Anesthesia for cardiac surgery has traditionally been provided with high-dose opioids and long-acting muscle relaxants, in the belief this technique was associated with optimal haemodynamic stability (blood circulation). However, these drugs could stay much more longer in the body after the cardiac surgery . This leads to prolonged postoperative mechanical ventilation (assisted breathing) and increased length of stay in the intensive care unit (ICU). This was considered to be an acceptable compromise; however, rising costs and the need for faster ICU turnover in the face of increased demand and reduced resources led the focus to reducing the length of ICU stay after cardiac surgery. Reducing postoperative mechanical ventilation was identified as a key factor for reducing ICU length of stay. Since the mid-1990s, intensified postoperative rehabilitation has established itself as the best approach to patient recovery and it was called fast-track treatment. Fast-track treatment has become a popular and accepted standard because it allows for early end of mechanical ventilation (extubation) within six hours and consequently reduced length of stay in the ICU and hospital. A significant reduction in time to extubation without compromising patient safety has been shown. However, earlier extubation has not always led to a reduction in ICU length of stay. Studies have shown that the implementation of a dedicated fast-track protocol allows not only for earlier extubation but also for earlier transfer from the ICU or the postoperative anesthesia care unit (PACU) to a step down unit. Utilised in combination, this approach has been associated with both significant cost savings and also increased ICU bed capacity. Most fast-track treatment protocols for cardiac surgery patients to date, however, have been implemented within the conventional ICU setting and not in a PACU. This study aims to compare the effectiveness of the fast-track protocol executed in a PACU and in an ICU.

Who can participate?
Patients scheduled to undergo cardiac surgery.

What does the study involve?
Patients were randomly allocated to one of two groups, either the PACU group or the ICU group, and were treated with the same fast-track protocol. The fast-track protocol included early extubation and mobilisation of the patients. All patients were transferred to PACU/ICU mechanically ventilated. Postoperative analgesia (pain killers) consisted of opioids, plus regular paracetamol to achieve tolerable postoperative pain for patients. The primary goal was to get the patients in a condition were they were conscious and followed commands, had stable spontaneous ventilation, were hemodynamically stable, not bleeding, and with no abnormalities of heart rhythm (ECG). Criteria for discharge to the intermediate care unit (IMC) were that patients must be awake, cooperative, and had stable function of the cardiovascular system and the lung.

What are the possible benefits and risks of participating?
For patients treated in the PACU earlier recovery of all functions is expected compared to patients treated in ICU. No additional risks are expected for fast-track treatment.

Where is the study run from?
University Hospital Leipzig, Germany.

When is the study starting and how long is it expected to run for ?
The study ran from May 2008 until September 2009.

Who is funding the study?
University of Leipzig, Germany

Who is the main contact?
Dr Stefan Probst, University Hospital Leipzig, Department of Anesthesia
stefan.probst@web.de

Contact information

Type(s)
Scientific

Contact name
Mr Christof Cech

Contact details
Struempellstrasse 39
Leipzig
Germany
02489

Additional identifiers

Study information

Scientific Title
A specialized post anesthetic care unit improves Fast-Track-Management in cardiac surgery: a prospective randomized trial

Study objectives
Treatment of patients with the same fast track protocol in a postoperative anesthetic care unit compared to ICU will reduce postoperative mechanical ventilation as well as postoperative anesthetic care unit stay compared to ICU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commitee, Medical Faculty, University of Leipzig, Haertelstrasse 16-18, 04107 Leipzig, 03 /04/2008, ref: 097-2008

Primary study design
Interventional

Study design
Prospective randomized trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anesthetic fast track protocol in cardiac surgery

Interventions
An anesthetic fast track protocol for cardiac surgery patients will be compared for patients passing trough an postoperative anesthetic care unit and a ICU.

Treatment for both groups contains:
1. Oral premedication with dipotassium-clorazepate (20-40 mg) the evening before and midazolam (3.75-7.5 mg) on the day of surgery
2. Induction of anaesthesia with fentanyl (0.2 mg), propofol (1.5-2 mg/kg) and a single dose of rocuronium (0.6 mg/kg)
3. Analgesia was maintained throughout the case with a continuous infusion of remifentanil (0.2 mcg/kg/min), and for hypnosis during the pre- and post-cardiopulmonary bypass (CBP) period sevoflurane (0.8 1.1 MAC) was administered whereas during CPB a continuous propofol infusion (3 mg/kg/h) was used.
4. Postoperative analgesia consisted of an bolus of piritramide (0.1 mg/kg) on discontinuation of the remifentanil infusion, followed by bolus doses as required in 2-4 mg aliquots, plus regular paracetamol (1 g every 6 hours) to achieve a pain score between 2 to 4 on an analogue pain scale from 0 to 10.
5. Patients were extubated when they were conscious and obeyed commands, had stable spontaneous ventilation with pressure support 10-12 cmH2O, PEEP 5 cmH2O, FiO2 ≤ 0.4, were hemodynamically stable, not bleeding (≤100 ml/hr), and with no significant electrocardiographic abnormalities

The total duration of treatment was expected u to 24 hours. Patients were followed up until discharge from hospital.

Intervention Type

Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Extubation time and Postanesthesia Care Unit (PACU)/Intensive Care Unit (ICU) length of stay (LOS). Primary endpoints will be measured from the time point were the patient reaches PACU /ICU.

Key secondary outcome(s)
1. Hospital LOS
2. Overall length of intensive care treatment (Total ICT LOS)
3. In-house mortality
4. Low cardiac output
5. New onset cardiac arrhythmia, respiratory failure requiring prolonged ventilation or re-intubation and incidences of surgical re-exploration and renal failure.

Secondary endpoint hospital length of stay is measured from the time were patient were admitted to the hospital. Total ICT LOS is measured from admitting the patient to PACU/ICU All other secondary outcomes are measured at baseline.

Completion date
30/09/2009

Eligibility

Key inclusion criteria
Every patient scheduled to undergo CABG, valve surgery, or combined CABG and valve surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who were in cardiogenic shock
2. Were dialysis dependent
3. Had an additive EuroSCORE of more than 10

Date of first enrolment
01/05/2008

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
Germany

Study participating centre
Struempellstrasse 39
Leipzig
Germany
02489

Sponsor information

Organisation
University Hospital Leipzig (Germany)

ROR
https://ror.org/028hv5492

Funder(s)

Funder type
University/education

Funder Name
Heart Center Leipzig - University of Leipzig (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	15/08/2014	Yes	No