

# 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

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<b>Registration date</b> 11/03/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/08/2014	<b>Condition category</b> Surgery	<input type="checkbox"/> 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 where 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  
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## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Christof Cech

**Contact details**

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## Additional identifiers

**Protocol serial number**

N/A

## 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 Committee, Medical Faculty, University of Leipzig, Haertelstrasse 16-18, 04107 Leipzig, 03/04/2008, ref: 097-2008

## Study design

Prospective randomized trial

## Primary study design

Interventional

## 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 through 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 remifentanyl (0.2 mcg/kg/min), and for hypnosis during the pre- and post-cardiopulmonary bypass (CPB) 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 remifentanyl 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 cmH<sub>2</sub>O, PEEP 5 cmH<sub>2</sub>O, FiO<sub>2</sub> ≤ 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?
<a href="#">Results article</a>	results	15/08/2014		Yes	No