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# LEVOsimendan before Heart-Lung-Machine in coronary artery bypass graft operations

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|---|---|---|
| **Submission date**<br>04/02/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>11/04/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>20/05/2014 | **Condition category**<br>Circulatory System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

**Acronym**
LEVOHLM

**Study objectives**

The goal of the study is to confirm the improvement of the Sepsis-related Organ Failure Assessment Scores (SOFA Score) with infusion of levosimendan compared with placebo in high risk patients undergoing coronary artery bypass graft-operations.

The following hypothesis will be tested:
H0 (null hypothesis): SOFA (levosimendan) equal to SOFA (placebo)
HA (alternative hypothesis - two-sided): SOFA (levosimendan) not equal to SOFA (placebo)

As of 08/05/2009 this record was updated to include amended participant criteria - for full details go to the relevant fields. At this time, the anticipated end date of this trial was also extended; the initial anticipated end date at the time of registration was 01/02/2010.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of Berlin (Landesamt für Gesundheit und Soziales Geschäftsstelle der Ethik-Kommission des Landes Berlin), 28/12/2007.

## Study design
Prospective randomised placebo-controlled double-blinded two-arm single-centre trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Coronary artery disease/coronary artery bypass graft operations

## Interventions
Levosimendan (Simdax®) group: continuous application of levosimendan at 0.1 µg/kg body weight/min (concentration of the applied solution: 250 µg/ml levosimendan, 5% glucose), cumulative dose: 72 µg/kg body weight
Placebo group: 5% glucose and Soluvit® (multivitamin solution for colouring the medication)

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Levosimendan

## Primary outcome(s)
The Sepsis-related Organ Failure Assessment (SOFA) score to describe organ dysfunction /failure. The SOFA score will be measured daily during the patient's stay in the Intensive Care Unit (ICU).

### Key secondary outcome(s))
1. Haemodynamic values throughout surgery and during patient's stay in the ICU
2. Doses and duration of therapy with catecholamines
3. Echocardiographic parameter during surgery
4. Delta-creatinine clearance before and after surgery
5. Horowitz (oxygenation) index, measured every 12 hours during patient's stay in the ICU
6. Serum lactate values during surgery and patient's stay in the ICU
7. Survival after 30 days and after 6 months
8. Incidence and frequencies of haemodialysis during patient's stay in the ICU
9. Incidence and frequencies of hemodialysis after fulfilling ICU discharge criteria up to hospital discharge
10. Quality of life 6 months after surgery

### Completion date
31/03/2012

## Eligibility

### Key inclusion criteria
Amended as of 08/05/2009:
Point seven below is no longer an inclusion criteria and should be disregarded.

Initial information at time of registration:
1. Offered patient information and obtained informed consent
2. Aged over 18 years old
3. Negative pregnancy test or anamnestically more than two years post-menopausal
4. No participation in another drug study according to the pharmaceutical law
5. Patients undergoing elective coronary artery bypass graft-surgery because of ischaemic cardiomyopathy with or without heart valve repair
6. Left ventricular ejection fraction less than or equal to 30%
7. Compensated renal insufficiency (creatinine greater than 1.14 mg/dl)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria

Amended as of 08/05/2009:
The following point has been amended:
10. Therapy with oral antidiabetics discontinued at least 36 hours before surgery

Initial information at time of registration:
1. Age under 18 years old
2. Pregnancy or lactation
3. Lacking willingness to save and hand out pseudonymised data within the study
4. A patient is admittted to an institution because of an official or medical order (according to German Medicines Act [AMG] Sectoin 40 (1) 4)
5. Liver disease (Child B or C cirrhosis, acute disease, End-Stage Liver Disease [MELD] score greater than 17)
6. Recent oesophageal or upper airway surgery
7. Severe oesophageal disease
8. Severe disease of the upper airways
9. Neurological/psychiatric disease
10. Therapy with oral antidiabetics
11. Infection with human immunodeficiency virus (HIV)
12. Active hepatitis B or C
13. Unclear history of alcohol related disorder

### Date of first enrolment
05/02/2008

### Date of final enrolment
31/03/2012

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Charitéplatz 1**
Berlin
Germany
10117

## Sponsor information

### Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

### ROR
https://ror.org/001w7jn25

# Funder(s)

### Funder type
University/education

### Funder Name
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (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 | 01/06/2014 | | Yes | No |