

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

Submission date 04/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/05/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

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 admitted to an institution because of an official or medical order (according to German Medicines Act [AMG] Section 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