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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
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).

Secondary outcome measures
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

Overall study start date
05/02/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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)

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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