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A pilot study of a goal-directed haemodynamic protocol comparison by monitoring with LiDCOrapid or oesophageal Doppler and conventional therapy during liver resection

Submission date
10/03/2009

Recruitment status
No longer recruiting

Registration date
03/12/2009

Overall study status
Completed

Last Edited
20/07/2015

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Intra-operative comparison of a goal-directed haemodynamic protocol by monitoring with LiDCOrapid or oesophageal Doppler and conventional therapy during liver resection: a prospective, randomised, controlled, blinded, three-armed single-centre pilot study

Study objectives
Compared to conventional therapy an intra-operative goal-directed haemodynamic management by monitoring with LiDCOrapid or oesophageal Doppler improves haemodynamics measured by stroke volume (SV) in patients undergoing elective liver resection.

As of 03/11/2010 this record has been updated to include an extended overall trial end date; the initial overall trial end date was 01/03/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin, 22/01/2009

Study design
Prospective randomised controlled blinded three-armed single-centre pilot 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
Elective liver resection surgery

Interventions
The interventions will take place only during liver resection:
1. Conventional intra-operative haemodynamic management
2. Intra-opertive LiDCOrapid-guided haemodynamic management
3. Intra-operative oesophageal Doppler-guided haemodynamic management

The last study day of the patient will be on the post-operative day 8 or on the day of hospital discharge (less than 8 post-operative days).

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Stroke volume before intra-operative start of liver resection

Secondary outcome measures
All determined within the study period of 8 post-operative days:
1. Intra-operative and post-operative haemodynamic parameters
2. Intra-operative and post-operative blood loss
3. (Cumulative) frequency of organ dysfunctions (cerebral, pulmonal, renal, abdominal, cardiovascular)
4. Post-operative liver function (LiMAx-test, ICG-Clearance, liver Doppler, laboratory tests: enzymatic and chemical parameters)
5. Peri-operative weight change
6. Post-operative incidence of infections
7. Satisfaction of the patients, the surgeons and anaesthetists
8. Time to fulfilling discharge criteria
9. Length of intensive care stay and hospital stay (LOS)
10. Quality of life measure (EQ-5D)
11. Laboratory tests: peri-operative endothelial and immunological alterations

Overall study start date
01/03/2009

Completion date
29/08/2010

Eligibility

Key inclusion criteria
Patients aged 18 years and over, either sex, undergoing elective liver resection in Charité - University Medicine Berlin, Campus Virchow-Clinic

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
60

Key exclusion criteria
1. Aged less than 18 years
2. No written informed consent from patient
3. For female patients: pregnancy or lactation
3. Inability to communicate freely in the German language
4. Lack of willingness to safe and hand out pseudonymised data within the clinical study
5. Simultaneous participation of the patient in another study
6. Accommodation in an institution due to an official or judicial order
7. Members of staff of the Charité
8. Unclear history of alcohol used disorder
9. Advanced disease of the oesophagus of nasopharyngeal cavity
10. Operations in the area of the oesophagus or nasopharynx within the last two months
11. History of bleeding tendency e.g. Von Willebrands disease
12. Neurological or psychiatric disease
13. Chronic heart failure New York Heart Association (NYHA) class IV
14. American Society of Anaesthesiologists (ASA) classification greater than IV
15. Chronic renal failure with dependency of haemodialysis
16. Existence of a pulmonary oedema in the pre-operative chest x-ray
17. History of intracranial haemorrhage within one year
18. Allergy to gelatin

Date of first enrolment
01/03/2009

Date of final enrolment
29/08/2010

Locations

Countries of recruitment
Germany

Study participating centre
Augustenburger Platz 1
Berlin
Germany
13353

Sponsor information

Organisation

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

Sponsor details
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10117
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Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charité Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
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	17/07/2015		Yes	No