

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	<input type="checkbox"/> Prospectively registered
Registration date 03/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/07/2015	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Claudia Spies

Contact details
Augustenburger Platz 1
Berlin
Germany
13353
-
claudia.spies@charite.de

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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-operative 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(s)

Stroke volume before intra-operative start of liver resection

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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