

Balanced crystalloids versus balanced colloids within a goal-directed haemodynamic protocol in patients undergoing gynaecological tumour resection

Submission date 14/07/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/09/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study will recruit 50 women with metastatic ovarian carcinoma (ovarian cancer that has spread) undergoing a tumour reduction operation. Colloid and crystalloid solutions are given into a patient's vein (intravenously) during surgery to maintain blood volume. The aim of this study is to find out whether a colloid solution is better than a crystalloid solution for volume replacement (i.e. a lower amount of solution is needed).

Who can participate?

Women aged 18 or over with metastatic ovarian carcinoma undergoing a tumour reduction operation at the University Hospital, Campus Virchow-Klinikum of the Charité - University Medicine Berlin

What does the study involve?

Participants are randomly allocated to receive either a colloid or crystalloid solution intravenously during their surgery. The amount of fluid used is measured, along with other factors such as length of intensive care and hospital stay, complications, pain and quality of life.

What are the possible benefits and risks of participating?

There are no additional treatments or tests for the participants, and the study drugs are common medicines used in everyday hospital routine. The risk to participants is low and there is a low risk of side effects to the study drugs.

Where is the study run from?

Charité - University Medicine Berlin (Germany)

When is the study starting and how long is it expected to run for?

May 2009 to June 2011

Who is funding the study?
Charité - University Medicine Berlin (Germany)

Who is the main contact?
Prof. Claudia Spies

Contact information

Type(s)
Scientific

Contact name
Prof Claudia Spies

Contact details
Augustenburger Platz 1
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Additional identifiers

Protocol serial number
EK 12 581/08

Study information

Scientific Title
Balanced crystalloids versus balanced colloids within a goal-directed haemodynamic protocol in patients undergoing gynaecological tumour resection: a prospective, randomised, controlled, double-blinded, two-armed single-centre trial

Acronym
BalaCriCo

Study objectives
A balanced colloid solution is superior to a balanced crystalloid solution for volume replacement in regard of lower amounts of intra-operatively administered intravenous solutions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Landesamt für Gesundheit und Soziales Berlin (LaGeSo), Germany, 19/12 /2008, ref: EK 12 581/08

Study design
Prospective randomised controlled double-blinded two-armed single-centre phase IV trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gynaecological tumour resection

Interventions

During gynaecological tumour resection:

1. Intra-operative oesophageal Doppler guided fluid management with a balanced colloid solution
2. Intra-operative oesophageal Doppler guided fluid management with a balanced crystalloid solution

The dosage will be guided by the stroke volume and the corrected flow time of the heart measured by the oesophageal Doppler. The duration of the study protocol identical to the administration of the study medication is from the beginning of the operation up to the end of the operation. Total intravenous Dose per day is 50 ml/kg BW/d for Volulyte and 50 ml/kg BW per day for Jonosteril. Follow up will be 3 months after drug application for all arms.

Intervention Type

Procedure/Surgery

Phase

Phase IV

Primary outcome(s)

Differences of intra-operatively administered amount of intravenous fluids (balanced colloid versus balanced crystalloid solutions) within a goal-directed haemodynamic management

Key secondary outcome(s)

1. Doses and duration of therapy with catecholamines measured intra-operatively and post-operatively during intensive care unit (ICU) stay
2. Time and number of hypotensive episodes measured intra-operatively and post-operatively during ICU stay
3. The quantity of intravenous fluid administered to the patient during the first 18 hours after surgery
4. The quantity of fluids per day lost by drainage during the first three days after surgery
5. Time that discharge criteria were met (measured by Post-Anaesthetic Discharge Scoring System [PADSS])
6. Length of intensive care stay and length of hospital stay (LOS)
7. The rate of post-operative organ dysfunctions and complications (cardiac, pulmonary, renal, gastrointestinal)
8. The rate of post-operative delirium and the post-operative incidence of post-operative, cognitive dysfunction
9. Weight change until the fifth post-operative day
10. Peri-operative incidence of infections (according to the Centers for Disease Control and Prevention [CDC] and American Thoracic Society [ATS] criteria)
11. Patient, surgeon and anaesthetic satisfaction

12. Pain of the patient
13. Quality of life measured before the operation, at the day of hospital discharge and three months after surgery
14. Laboratory tests: peri-operative endothelial and immunological alterations

The secondary outcome measures were determined if above not specified within the study up to the 10th post-operative day.

Completion date

30/06/2011

Eligibility

Key inclusion criteria

1. Female patients aged 18 and over
2. Patients with metastatic ovarian carcinoma undergoing a tumour reduction operation at the University Hospital, Campus Virchow-Klinikum of the Charité - University Medicine Berlin
3. Offered patient information and written informed consent
4. No participation in another clinical trial during the trial until the 10th post-operative day

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Aged less than 18 years
2. Pregnancy or lactation
3. Lacking willingness to save and hand out pseudonymised data within the clinical study
4. Accommodation in an institution due to an official or judicial order
5. Advanced disease of the oesophagus or nasopharyngeal cavity
6. Operations in the area of the oesophagus or nasopharynx within the last two months
7. Liver disease (Child B or C cirrhosis, end-stage liver disease [MELD] score greater than 10)
8. Conditions after acute or chronic pancreatitis
9. History of bleeding tendency, e.g. Von Willebrands disease
10. Neurological or psychiatric disease
11. Unclear history of alcohol related disorder
12. Chronic heart failure class IV according to the New York Heart Association (NYHA)
13. American Society of Anaesthesiologists (ASA) classification greater than III
14. Renal insufficiency (serum creatinine greater than 2.0 mg/dl or greater than 150 µmol/l or

dependency of haemodialysis)

15. Existence of a pulmonary oedema in the pre-operative chest x-ray
16. Allergy to hydroxyethyl starch or other ingredients of the intravenous solutions
17. History of intracranial haemorrhage within one year before participation in the study
18. Hyperkalaemia greater than 5.8 mmol/l and hypernatraemia greater than 155 mmol/l
19. Pre-operative ileus symptomatology
20. Known history of hypermagnesaemia
21. Known history of metabolic alkalosis
22. Derailed diabetes mellitus (glucose greater than 300 mg/dl) before inclusion

Date of first enrolment

01/05/2009

Date of final enrolment

30/06/2011

Locations

Countries of recruitment

Germany

Study participating centre

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin)

Berlin

Germany

13353

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 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	01/02/2013		Yes	No
Results article	substudy results	01/07/2017		Yes	No