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

Submission date
14/07/2009

Registration date
27/08/2009

Last Edited
22/09/2017

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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

Secondary outcome measures

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 admininstered 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 dysfuntions and complications (cardiac, pulmonal, 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.

Overall study start date
01/05/2009

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

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
50

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 of 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 hypernatriaemia 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)

Sponsor details
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Sponsor type
University/education

Website
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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

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