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Coagulation Effect of Anesthesia

Submission date	Recruitment status	[ ] Prospectively registered
06/12/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/12/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/09/2020	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During surgery and fluid therapy, blood clotting changes. Fluid therapy expands and dilutes the plasma (a component of blood) and different constituents of the plasma. Fluid therapy may be necessary in situations of blood loss, dehydration prior to surgery or anesthetic technique used during the surgery. The plasma dilution can affect the clotting of the blood in several aspects. When anesthesia is given, there is a redistribution of fluid in the body regardless of fluid is administered or not. In earlier studies we have found that only by giving colloids (substances that are dispersed throughout a liquid) at the start of anesthesia, the blood clotting is changed. However, we did not see any major differences between different colloids. The differences were found with the dilution, than with any other factor. In this study we wish to study the effects of induction of anesthesia. Further we wish to study if there is a difference in the clotting of the blood if fluid therapy is given or not, during the induction of the anesthesia.

Who can participate?
Patients over 18 years of age who have had their gall bladder removed can participate in the study.

What does the study involve?
Patients are randomly allocated to receive fluid therapy or not. Those patients allocated to fluid therapy will receive fluid infusion during the induction of anesthesia. Others will not receive fluid therapy unless required. Blood samples will be taken before and after start of anesthesia to study blood clotting.

What are the possible benefits and risks of participating?
If unexpected clotting defects are found these can be dealt with early, before major bleeding occurs.

Where is the study run from?
The study will take place at the operation ward at Norrköping Hospital, Sweden.

When is the study starting and how long is it expected to run for?
The study starts in December 2013 and is expected to finish in June 2015.

Who is funding the study?
The study is funded by the Östergötland County Council, Sweden.

Who is the main contact?
Dr Joachim Zdolsek
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Contact information

Type(s)
Scientific

Contact name
Dr Joachim Zdolsek

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Department of Anesthesia and Intensive Care
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CEA

Study information

Scientific Title
Coagulation effect of induction of anesthesia

Acronym
CEA

Study objectives
The primary hypothesis is that the fluid volume redistribution that occurs during induction of anesthesia influences the clotting of the blood.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethics committée in Linköping, Dnr 2010/240-31, 11/08/2010

Study design
Prospective controlled randomized open clinical study

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
Changes in coagulation during induction of anesthesia in elective surgery: cholecystectomy

Interventions
40 patients subjected to cholecystectomy during general anesthesia are asked to participate in the study, during preanesthetic evaluation. 40 envelopes are placed in a box. The envelope picked decides to which group the patient will be randomized. One group (20 patients) will receive fluid infusion during induction of anesthesia. In the other group (20 patients) fluid will as far as possible be avoided. In case of hypotension, these patients will first receive ephedrine and Trendelenburg tilt. If this does not help, fluid infusion is started.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Qualitative analysis of blood clotting by rotational trombelastometry (ROTEM). Blood samples are collected prior to anesthesia and 15 minutes after induction of anesthesia.

Secondary outcome measures
All other clotting tests performed before and 15 minutes after induction of anesthesia:
1. Hemoglobin (Hgb)
2. Albumin
3. Thrombin antthrombin complex (TAT)
4. D-dimer
5. Soluble P-selectin
6. Activated partial thrombin time (APTT)
7. Prothrombin time (PT) and international normalized ratio (INR)
8. Platelets

Overall study start date
15/12/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Patients over the age of 18, belonging to American Society of Anaesthesiologists (ASA) physical status classification score groups I and II
2. Patients operated with cholecystectomy
3. Patients signing informed consent after oral and written information

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Regional anesthesia
2. Age less than 18 years
3. Pregnancy
4. ASA group III and IV
5. Cardiac disease
6. Known kidney failure (creatinine >170)
7. Rheumatoid arthritis
8. Treatment with anticoagulants

Date of first enrolment
15/12/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Anesthesia and Intensive Care
Linköping
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58185

Sponsor information

Organisation
Linköping University Hospital (Sweden)

Sponsor details
c/o Joachim Zdolsek
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58185

Sponsor type
Hospital/treatment centre

Website
http://www.lio.se/

ROR
https://ror.org/05h1aye87

Funder(s)

Funder type
Government

Funder Name
Östergötland City Council (Sweden)

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