

Coagulation Effect of Anesthesia

Submission date 06/12/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 31/12/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/09/2020	Condition category Surgery	☐ Individual participant data ☐ 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
joachim.zdolsek@lio.se

Contact information

Type(s)
Scientific

Contact name
Dr Joachim Zdolsek

Contact details
Department of Anesthesia and Intensive Care
Linköping University Hospital
Linköping
Sweden
58185

Additional identifiers

Protocol serial number
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 committee in Linköping, Dnr 2010/240-31, 11/08/2010

Primary study design
Interventional

Study design

Prospective controlled randomized open clinical study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

All other clotting tests performed before and 15 minutes after induction of anesthesia:

1. Hemoglobin (Hgb)
2. Albumin
3. Thrombin antithrombin 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Sweden

58185

Sponsor information**Organisation**

Linköping University Hospital (Sweden)

ROR

<https://ror.org/05h1aye87>

Funder(s)

Funder type

Government

Funder Name

Östergötland City Council (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration