ISRCTN62203940 https://doi.org/10.1186/ISRCTN62203940

Hypercoagulation effect evaluation and deep vein thrombosis preventions after laparoscopic surgery.

Submission date
02/11/2014

Recruitment status
No longer recruiting

Registration date
29/12/2014

Overall study status
Completed

Last Edited
29/12/2014

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Venous thromboembolism (VTE) is a serious, potentially fatal, medical condition where people develop a blood clot in a vein. People who have just had major surgery are at particular risk of VTE; between 20-30% of VTE patients have just had general surgery. About 5.5% of VTE patients have undergone laparoscopic fundoplication, a “keyhole” surgery for treating gastro-oesophageal reflux disease. Here, we want to test whether treating patients with Bemiparin (Zibor) before patients have their laparoscopic fundoplication surgery reduces the risk of deep vein thrombosis (DVT), a blood clot in a leg vein. We will be investigating two different treatment regimens to see which one works best.

Who can participate?
Adult patients between 18-75 years undergoing laparoscopic fundoplication surgery.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive one dose (2500 TV 0,2 ml.) of Bemiparin and intraoperative intermittent pneumatic compression (IPC – a therapy whereby an inflatable device squeezes fluids, such as blood, out of the area where it is applied) one hour before their operation. Those in group 2 receive 3 doses of Bemiparin, one 12 hours before the operation, one 6 hours after the operation and a final dose 30 hours after the operation. IPC is also applied during the surgery. After the operation, the blood is tested for certain components (markers) that would suggest a blood clot is forming (thrombogenesis) and other components that would suggest that the blood is not able to clot (hypocoagulation). These are measured 1 hour before, during, just after and then 2 days after the operation. Deep vein imaging methods are also used to check for DVT before the operation, 2 days afterwards and finally 28 days after the surgery.

What are the possible benefits and risks of participating?
There are no additional risks to taking part in the study.

Where is the study run from?
The Hospital of Lithuanian University of Health Sciences (LUHS) (Lithuania)

When is the study starting and how long is it expected to run for?
January 2014 to January 2017

Who is funding the study?
The Lithuanian University of Health Sciences (LUHS) (Lithuania)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Hypercoagulation effect evaluation and deep vein thrombosis preventions after laparoscopic surgery: a prospective randomized double blinded trial.

Acronym
N/A

Study objectives
A combination of one dose low-molecular-weight heparin (LMWH) 1h before laparoscopic surgery with intraoperative intermittent pneumatic compression (IPC) causes better hypocoagulation effect that LMWH administered 12h before surgery with intraoperative IPC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Biomedical Research Ethics Committees in Lithuania: in Kaunas region (based at the Lithuanian University of Health Sciences), 08/10/2014, ref. Nr. BE-2-13.

Study design
Prospective randomized double blinded trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with hiautus hernia diagnosis and condition after laparoscopic fundoplications.
The study domain is to evaluate the hypocoagulation effect and rate of deep vein thrombosis complications of intermittent pneumatic compression (IPC) combination of low molecular weight heparin (LMWH) after laparoscopic fundoplication

Interventions
The participants were randomly allocated into one of two groups:
Group 1 received subcutaneous 2500 TV 0,2 ml LMWH Bemiparin (Zibor) - one dose (1h before the operation)
Group 2 received three doses of 2500 TV 0,2 ml LMWH Bemiparin (Zibor) - (12h before the operation, 6h and 30h after the operation).

Blood sampling:
Venous blood samples were taken (obtained) from the forearm vein four times:
1. 1h. before the operation (before LMWH injection)
2. 1h after the introduction of the laparoscope
3. After extubation
4. 2 days after the operation

Imaging methods:
1. Duplex examination - before the operation, two days after the operation and 28 days after the operation
2. Spiral CT venography two days after the operation.

Intervention Type

Phase
Not Applicable

Primary outcome(s)
1. F1+2 and TAT concentrations in plasma samples were measured by solid phase sandwich ELISA method (Enzygnost® F1+2 and Enzygnost® TAT microenzyme immunoassay, Dade Behring, Germany).
2. fTFPI was performed by an ELISA technique (Diagnostika Stago, France) according to the manufacturers instructions.
3. Thromboelastograma - TEG measures the physical properties of the clot in whole blood via a

pin suspended in a cup (heated to 37C) from a torsion wire connected with a mechanical electrical transducer; koalin is used as activator.

Key secondary outcome(s))
Ultrasound examination - Toshiba Aplio SSA 770A - compression ultrasound (B-mode imaging only), duplex ultrasound (B-mode imaging and Doppler waveform analysis), and color Doppler imaging alone. Different lower extremity veins are best evaluated with different techniques: compression ultrasound is typically performed on the proximal deep veins - the common femoral, femoral, and popliteal veins, whereas a combination of duplex ultrasound and color Doppler imaging is more often used to interrogate the calf and iliac veins.
Spiral CT venography - GE Light Speed Pro (320 slice) - using 150 mL of IV contrast - 4 mL/sec, with a delay three minutes after the start of injection, 5-mm thick axial CT venograms are acquired from the ankles to the mid abdomen.

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Patients undergoing elective laparoscopic fundoplications because of gastroesophagial reflux disease, caused by hiatus hernia.
2. The patients in the two groups are similar in terms of age (18 - 75 years), weight, height, gender, duration of surgery and ASA score.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with coagulopathies disorders
2. Usage of prescription drug modifying cardiovascular response
3. Participants with systemics nervous system disease
4. Pregnant women
5. Patients, who refused to participate in the study

Date of first enrolment
01/01/2014

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Lithuania

Study participating centre
S. Ciurlionienes-Kymantaites str. 7
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Sponsor information

Organisation
The Lithuanian University of Health Sciences (LUHS) (Lithuania)

ROR
https://ror.org/0069bkg23

Funder(s)

Funder type
University/education

Funder Name
The Lithuanian University of Health Sciences (LUHS) (Lithuania)

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?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes