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Effects of prolonged anti blood clot treatment after colorectal surgery

Submission date	Recruitment status	[_] Prospectively registered
03/07/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/07/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/02/2021	Surgery	

Plain English summary of protocol

Background and study aims
Blood clots are a common complication after surgery on the colon and rectum, especially when performed for cancer or inflammatory bowel disease. While in the hospital, patients receive a shot of blood thinners to lower the risk. It is generally recommended that patients who are considered high risk continue this when they go home, but it is not done routinely, leading to rates of blood clots still being high. The aim of this study is to see whether giving all patients undergoing colorectal surgery shots at home after surgery is safe and lowers the risk of blood clots.

Who can participate?
Patients undergoing colon and rectal surgery at the division of colorectal surgery at BIDMC

What does the study involve?
All patients are sent home with 30 days of shots of blood thinner from the time of surgery, starting from when they were in the hospital. Patients and family are taught how to do the shots. Visiting nurses also arrange to come to the patients' homes to help with injections and more teaching.

What are the possible benefits and risks of participating?
Participating may decrease the chance of blood clots.

Where is the study run from?
Beth Israel Deaconess Medical Center (BIDMC), Boston, MA (USA)

When is the study starting and how long is it expected to run for?
August 2017 to December 2018

Who is funding the study?
Not funded – this is a quality improvement project, costs of medications and visiting nurses are covered by insurance

Who is the main contact?
Dr Vitaliy Poylin
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BIDMC 2

Study information

Scientific Title
Minimal effect of universal extended prophylaxis on rates of venous thromboembolic events after colorectal surgery in a tertiary care center. Is compliance the problem?

Study objectives
Extended VTE (venous thromboembolism) prophylaxis is safe after colon and rectal surgery and will decrease overall rates of VTE.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/19/2018, Institutional Review Board at Beth Israel Deaconess Medical Center (330 Brookline Ave., Boston, MA 02115, USA; Email: jripton@bidmc.harvard.edu)

Study design
Prospective quality improvement trial, comparison to historic controls

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colon and rectal surgery, venous thromboembolism

Interventions
Universal extended (30 days after surgery) prophylaxis with enoxaperin. Enoxaparin dose was weight based and used for 30 days after surgery. Survey was done 30 days after surgery.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Enoxaperin

Primary outcome(s)
1. Complications from extended use of enoxaparin, measured using chart review and phone interview at 30 days after surgery
2. Compliance with extended prophylaxis regimen, measured using phone survey at 30 days after surgery

Key secondary outcome(s))
1. Rates of VTE measured using chart review and NSQIP data collection at 30 days after surgery
2. Other complications measured using chart review at 30 days after surgery

Completion date
31/01/2019

Eligibility

Key inclusion criteria
All patients undergoing colon and rectal surgery at BIDMC between 11/1/2017 and 10/31/2018

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
270

Key exclusion criteria
1. Patients with contraindication for use of low molecular weight heparin
2. Patients already on anticoagulation for other conditions

Date of first enrolment
01/11/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Beth Israel Deaconess Medical Center
330 Brookline Ave
Boston
United States of America
02215

Sponsor information

Organisation
Beth Israel Deaconess Medical Center

ROR
https://ror.org/04drvxt59

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Vitaliy Poylin (vitaliy.poylin2@nm.org).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	09/02/2021	Yes	No