

# Effects of prolonged anti blood clot treatment after colorectal surgery

<b>Submission date</b> 03/07/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/02/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## 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  
vitaliy.poylin2@nm.org

## Contact information

### Type(s)

Scientific

### Contact name

Dr Vitaliy Poylin

### ORCID ID

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## Additional identifiers

### 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](mailto: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?
<a href="#">Results article</a>	results	01/01/2021	09/02/2021	Yes	No