# Effects of prolonged anti blood clot treatment after colorectal surgery

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
03/07/2019		Protocol		
<b>Registration date</b> 10/07/2019	Overall study status Completed	Statistical analysis plan		
		[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 vitaliy.poylin2@nm.org

# **Contact information**

# Type(s)

Scientific

#### Contact name

Dr Vitaliy Poylin

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### IRAS number

# ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

#### Study type(s)

Treatment

# Participant information sheet

## 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 measure

- 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

# Secondary outcome measures

- 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

# Overall study start date

# 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** 

## Age group

All

#### Sex

Both

# Target number of participants

270

# 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

#### Sponsor details

330 Brookline Ave Boston United States of America 02215 +1 (0)617 667 7000 vpoylin@gmail.com

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/04drvxt59

# Funder(s)

# Funder type

Other

#### **Funder Name**

Investigator initiated and funded

# **Results and Publications**

# Publication and dissemination plan

Submitted to a journal for publication.

# Intention to publish date

01/12/2019

# 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