ISRCTN13851176 https://doi.org/10.1186/ISRCTN13851176

# The use of bemiparin to prevent deep vein thrombosis in plastic and reconstructive surgery patients

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 16/08/2019 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 27/08/2019 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 18/02/2020 | Circulatory System | |

## Plain English summary of protocol

Background and study aims
Deep vein thrombosis (DVT) is a blood clot that develops within a deep vein in the body, usually in the leg.It can cause pain and swelling in the leg and may lead to complications such as pulmonary embolism. This is a serious condition that occurs when a piece of blood clot breaks off into the bloodstream and blocks one of the blood vessels in the lungs.
DVT is a common complication during postoperative convalescence. Both the complexity and frequency of plastic and reconstructive surgery (PRSx) procedures have significantly increased in Mexico over the last 25 years. It has become necessary to find more effective measures to prevent DVT. The aim of this study was to evaluate the efficacy and safety of bemiparin compared to enoxaparin for the prevention of DVT

Who can participate?
Major plastic or reconstructive surgery patients at a high risk of developing thrombosis.

What does the study involve?
Following surgery patients will be randomly allocated to receive one of two, different anti-thrombotic drugs.

What are the possible benefits and risks of participating?
Benefits: DVT risk reduction. No ultrasound study is charged to any participant.
Risks: hematoma (localized bleeding outside of blood vessels), hyperkalemia (raised potassium in blood).

Where is the study run from?
American British Cowdray Santa Fe Medical Center, Mexico

When is the study starting and how long is it expected to run for?
April 2016 to April 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Revilla-Peñaloza
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# Contact information

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Scientific


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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
ABC-15-17

# Study information

### Scientific Title
Randomised trial of deep vein thrombosis chemoprophylaxis with bemiparin and enoxaparin in patients with moderate to high thrombogenic risk undergoing plastic and reconstructive surgery procedures

### Acronym
RATDEVETROBEMENOXA

### Study objectives
Compared to enoxaparin, perioperative administration of bemiparin reduces deep vein thrombosis risk without significantly increasing bleeding hazards in plastic and reconstructive surgery patients with moderate to high thrombogenic risk

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 08/10/2015, Institutional Research and Research Ethics Committees The American British Cowdray Medical Center (Sur 136, No.116 Colonia las Américas., Mexico City, 01120, Mexico; (52)5552308097; relacionespublicas_obs@abchospital.com), ref: ABC 15-17

### Study design
Single centre single blind randomized parallel trial

### Primary study design
Interventional

### Secondary study design
Randomised parallel trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

### Participant information sheet

No participant information sheet available

### Health condition(s) or problem(s) studied
Deep vein thrombosis (DVT) lower limbs

### Interventions
Six hours after the end of the surgical procedure patients were assigned according to a sequential list (each new patient was alternatively assigned to either treatment group by Dr. Juan Molina (outside reader) regardless of their anthropometric characteristics or clinical condition) for single-blind subcutaneous administration of either enoxaparin 40 IU (Group-E) or bemiparin 3500 IU (Group-B) every 24 hours (q24h). Low Molecular Weight Heparin (LMWH) treatment was delivered during at least 10 days.

All patients were evaluated for DVT through Doppler ultrasound mapping of the lower limbs.

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Bemiparin (Heporax) and enoxaparin (Clexane).

### Primary outcome measure
Lower limb thrombogenesis: using USG Sonosite Doppler Micromax and multifrequency linear transducer from 4 to 12 MHz, to study the pelvic limbs in transversal and longitudinal sections, which yielded images in both gray scale and color, and applying Valsalva maneuvers and compression in all superficial and deep veins to looking for Thrombosis or reflux at key points. Ultrasound studies were carried out 24 hours before and 3-5 days after surgery.

### Secondary outcome measures
Postoperative bleeding, measured using daily surgical drains. Timepoint: 4 days in mastoplasty cases; 15 days in abdominoplasty cases

### Overall study start date
18/03/2015

### Completion date
30/04/2018

## Eligibility

### Key inclusion criteria
1. Informed consent
2. Major plastic or reconstructive surgery patients
3. Moderate to high thrombogenic risk according to Caprini’s scale
4. Classified I-III according to American Society of Anesthesiology criteria

### Participant type(s)

Patient

### Age group
Adult

### Sex
Both

### Target number of participants
80 patients

### Total final enrolment
78

### Key exclusion criteria
1. Active bleeding
2. Heparin-induced thrombocytopenia
3. Platelet count under 100,000
4. Severe renal insufficiency
5. Coagulopathy
6. Recent intracranial surgery
7. Epidural anesthesia or lumbar puncture over the last 24 hours

### Date of first enrolment
01/05/2016

### Date of final enrolment
30/04/2018

## Locations

### Countries of recruitment
Mexico

### Study participating centre
**American British Cowdray Santa Fe Medical Center**
No. 154 Carlos Graef Fernandez Av.
Santa Fe
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## Sponsor information

### Organisation
Institutional Research and Research Ethics Committees The American British Cowdray Medical Center, Mexico City.

### Sponsor details
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### Sponsor type
Hospital/treatment centre

### Website
http://www.abchospital.com

### ROR
https://ror.org/03e36d037

## Funder(s)

### Funder type
Other

### Funder Name
Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan
Submission to either Clinical and Applied Thrombosis/Hemostasis Journal or Thrombosis and Hemostasis.

### Intention to publish date
30/08/2019

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as participants did not agree to make the data public.

### IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2020 | | Yes | No |