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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?
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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
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
Postoperative bleeding, measured using daily surgical drains. Timepoint: 4 days in mastoplasty cases; 15 days in abdominoplasty cases

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment

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
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Sponsor information

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

ROR
https://ror.org/03e36d037

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 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