

Compression stockings to prevent post-thrombotic syndrome: the SOX trial

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 01/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/11/2015	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00143598

Protocol serial number
MCT-63142

Study information

Scientific Title

Compression stockings to prevent post-thrombotic syndrome: a multicentre, two arm, placebo-controlled randomised parallel device trial

Acronym
SOX

Study objectives

To determine whether Elastic Compression Stockings (ECS) used for two years are effective in preventing the Post-Thrombotic Syndrome (PTS) in patients with symptomatic proximal Deep Venous Thrombosis (DVT).

Previous hypothesis:

To determine whether Elastic Compression Stockings (ECS) used for two years, and celecoxib, a COX-II inhibitor, used for 30 days are effective in preventing the Post-Thrombotic Syndrome (PTS) in patients with symptomatic proximal Deep Venous Thrombosis (DVT).

Sub -study registered with ClinicalTrials.gov: NCT01615705 - Biomarker Sub Study of the Compression Stockings to Prevent the Post-Thrombotic Syndrome (SOX) Trial (Bio-SOX)

Sub -study registered with ClinicalTrials.gov: NCT01615692 - The 36-month Extension to Follow up Sub Study

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Canada: The Research Ethics Committee of Sir Mortimer B Davis Jewish General Hospital, 30 /07/2003. This ethics approval was amended on 27/01/2005 to take into account the removal of the celecoxib intervention and consequent protocol changes.
2. USA: The University of Oklahoma Health Sciences Center Institutional Review Board (USA), 31 /07/2007, ref: 13513. All other centres subsequent to this in the USA will require full ethics approval before recruiting participants.

Primary study design

Interventional

Study design

Multicentre two-arm placebo randomised parallel device trial with study participant, study investigator, and outcome assessor blinded.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Deep vein thrombosis

Interventions

Current interventions (protocol updated in January 2005):

1. Experimental interventions: knee-length, 30 - 40 mmHg (Class II), graduated ECS worn on the DVT-affected leg daily, applied upon waking and removed upon retiring, beginning within a week (as soon as possible) after DVT diagnosis, and continued for two years
2. Control interventions: knee-length, inactive (i.e. no compression) stocking, identical in appearance to active ECS, worn on the DVT-affected leg daily, applied upon waking and removed upon retiring, beginning within a week (as soon as possible) after DVT diagnosis, and continued for two years

Previous interventions:

1. Experimental interventions:
 - 1.1. Knee-length, 30 - 40 mmHg (Class II), graduated ECS worn on the DVT-affected leg daily, applied upon waking and removed upon retiring, beginning within a week (as soon as possible) after DVT diagnosis, and continued for two years
 - 1.2. Celecoxib, 200 mg orally (po) twice a day (BID), begun on the day of DVT diagnosis and continued for 30 days
2. Control interventions:
 - 2.1. Knee-length, inactive (i.e. no compression) stocking, identical in appearance to active ECS, worn on the DVT-affected leg daily, applied upon waking and removed upon retiring, beginning within a week (as soon as possible) after DVT diagnosis, and continued for two years
 - 2.2. Placebo, identical in appearance to celecoxib, one tablet po BID, begun on the day of DVT diagnosis and continued for 30 days

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Incidence of post-thrombotic syndrome (PTS) at two years

Key secondary outcome(s)

Current secondary outcome measures (protocol updated in January 2005):

1. Severity of PTS at two years follow up, including incidence of venous ulcer
2. Incidence of objectively confirmed recurrent VTE, and death from VTE, over two years
3. C-reactive protein at 30 days compared to baseline value
4. Quality of life over the two-year follow up
5. Cost-effectiveness

Previous secondary outcome measures:

1. Severity of PTS at two years follow up, including incidence of venous ulcer
2. Incidence of objectively confirmed recurrent VTE, and death from VTE, over two years
3. Incidence of major bleeding or arterial thrombotic events during the first 60 days
4. C-reactive protein at 30 days compared to baseline value
5. Quality of life over the two-year follow up
6. Cost-effectiveness

Completion date

31/01/2012

Eligibility

Key inclusion criteria

Current inclusion criteria (protocol updated in August 2008):

Consecutive patients aged greater than or equal to 18 years old, either sex, with a first, symptomatic, objectively confirmed proximal DVT diagnosed within the last 14 days (with or without concurrent distal DVT or Pulmonary Embolism [PE]) who have no contraindications to standard treatment with heparin and/or warfarin, and who provide informed consent to participate.

Previous inclusion criteria (January 2005):

Consecutive patients aged greater than or equal to 18 years old, either sex, with a first, symptomatic, objectively confirmed proximal DVT diagnosed within the last 10 days (with or without concurrent distal DVT or Pulmonary Embolism [PE]) who have no contraindications to standard treatment with heparin and/or warfarin, and who provide informed consent to participate.

Initial inclusion criteria (January 2004):

Consecutive patients with a first, symptomatic, objectively confirmed proximal DVT diagnosed within the last 72 hours (with or without concurrent distal DVT or Pulmonary Embolism [PE]) who have no contraindications to standard treatment with heparin and/or warfarin, and who provide informed consent to participate.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Current exclusion criteria (protocol updated in January 2005):

1. Contraindication to compression stockings
2. Limited lifespan (estimated less than six months)
3. Geographic inaccessibility preventing return for follow-up visits
4. Inability to apply stockings daily and unavailability of a caregiver to apply stockings daily
5. Treatment of acute DVT with thrombolytic agents

Previous exclusion criteria:

1. Contraindication to compression stockings
2. Contraindication to celecoxib
3. History of warfarin, aspirin or Non-Steroidal Anti-Inflammatory Drug (NSAID)-associated major haemorrhagic event
4. Regular, daily use of NSAIDs
5. Inability/unwillingness to stop anti-platelet drugs for 30 days
6. Limited lifespan (estimated less than six months)
7. Geographic inaccessibility preventing return for follow-up visits
8. Inability to apply stockings daily and unavailability of a caregiver to apply stockings daily
9. Treatment of acute DVT with thrombolytic agents

Date of first enrolment

01/04/2003

Date of final enrolment

17/02/2010

Locations

Countries of recruitment

Canada

United States of America

Study participating centre

SMBD Jewish General Hospital

Montreal, Quebec

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Sponsor information

Organisation

Sir Mortimer B. Davis Jewish General Hospital-Mtl (Canada)

ROR

<https://ror.org/056jjra10>

Funder(s)

Funder type

Industry

Funder Name

Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

SIGVARIS Corp. (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/2014		Yes	No
Results article	results	01/12/2014		Yes	No
Protocol article	protocol	24/07/2007		Yes	No
Basic results				No	No