ISRCTN71334751 https://doi.org/10.1186/ISRCTN71334751

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

Submission date 01/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] 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

Contact name
Dr Susan Rebecca Kahn

Contact details
Center for Clinical Epidemiology and Community Studies
SMBD Jewish General Hospital
3755 Cote Ste. Catherine Rm A-127
Montreal, Quebec
Canada
H3T 1E2
+1 (0)514 3408222 (4667)
susan.kahn@mcgill.ca

Type(s)
Public

Contact name
Ms Susan Kahn

Contact details
SMBD Jewish General Hospital
3755 Cote Ste. Catherine Rm A-127
Montreal, Quebec
Canada

H3T 1E2
+1 (0)514 340 8222 ext. 4667
susan.kahn@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00143598

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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
Canada
H3T 1E2

Sponsor information

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

Sponsor details
3755 Côte Ste-Catherine Road
Montreal, Quebec
Canada
H3T 1E2
+1 (0)514 340 8222
wainberg@ldi.jgh.mcgill.ca

Sponsor type
Not defined

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, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
SIGVARIS Corp. (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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