ISRCTN56430072 https://doi.org/10.1186/ISRCTN56430072

Exercise training for the treatment of post-thrombotic syndrome: the EXPO pilot trial

Submission date 09/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2008	**Overall study status** Completed	
Last Edited 25/01/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Susan Rebecca Kahn

Contact details
Sir Mortimer B. Davis Jewish General Hospital
3755 Cote Ste. Catherine, rm A-127
Montreal, Quebec
Canada
H3T 1E2
+1 514 340 8222 ext. 4667
susan.kahn@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-82338

Study information

Scientific Title
Exercise training for the treatment of post-thrombotic syndrome: a multicentre, two-arm randomised controlled parallel trial

Acronym
EXPO

Study objectives
In our proposed pilot trial, we will randomise patients with post-thrombotic syndrome (PTS) to:
1. A six-month exercise training program designed to improve leg strength, leg endurance, leg flexibility and general cardiovascular fitness (Active Training), or
2. An Attention Control group

Our feasibility objectives are to assess levels of patient eligibility, consent, adherence and retention. Our scientific objectives are to obtain estimates of effect size associated with Active Training, by describing within-subject change over six months in quality of life (QOL), severity of PTS, calf strength, calf flexibility and exercise capacity (time-on-treadmill) in the Active Training and Attention Control groups. Our results will inform the design of a large, multicentre trial of exercise training to treat PTS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Sir Mortimer B. Davis Jewish General Hospital (Canada) approved on the 13th October 2006 (ref: 06-080).

Study design
Multicentre, two-arm randomised parallel trial with outcome assessor and data analyst blinding

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Post-thrombotic syndrome

Interventions

Active Training:
Six-month exercise training program designed to improve leg strength, leg endurance, leg flexibility and general cardiovascular fitness.

Attention Control:
Six-month program consisting of:
1. Standardised one-hour education session on PTS (what PTS is, why patients get it, how to manage it; exercise will be kept 'neutral', i.e., not specifically addressed) given by a trained thrombosis nurse-educator not involved with the assessment of study outcomes, and
2. Monthly phone contacts by the same thrombosis nurse to 'check in' with the patient, ask about their PTS and provide support

Contact for public queries:
Adrielle H. Houweling
Clinical Trial Coordinator, The EXPO Pilot Trial
Sir Mortimer B. Davis Jewish General Hospital
3755 Cote St. Catherine, rm. A-121
Montreal, Quebec
H3T 1E2
Canada
Tel: +1 514 340 8222 ext. 4717
Fax: +1 514 340 7564

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Feasibility indicators (measured throughout trial):
1. Proportion of patients screened who are eligible to participate in the trial
2. Proportion of eligible patients who consent to participate in the trial
3. Proportion of subjects who are adherent with the intervention
4. Proportion of subjects who complete the trial

Secondary outcome measures
1. Venous disease-specific, measured at baseline, 3 months and 6 months
2. Generic QOL, measured at baseline, 3 months and 6 months
3. Severity of PTS (Villalta PTS Scale), measured at baseline, 3 months and 6 months
4. Leg (triceps surae) strength, measured at baseline, 3 months and 6 months
5. Leg flexibility, measured at baseline, 3 months and 6 months
6. Time-on-treadmill, measured at pre-randomisation and 6 months

Overall study start date
01/03/2006

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Aged 18 - 75 years, either sex
2. Previous unilateral deep vein thrombosis (DVT) diagnosed using standardised ultrasound or venographic criteria
3. PTS in same leg as previous DVT (Villalta PTS Scale score greater than 4)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
44

Key exclusion criteria
1. Acute DVT within previous six months
2. Contra-indications to exercise training, e.g. arthritis of lower extremities, angina, symptomatic chronic obstructive lung disease, congestive heart failure, severe claudication, poor balance
3. Expected lifespan less than six months or general medical condition that would make study unfeasible, e.g. advanced cancer or cardiopulmonary disease
4. Pregnancy or lactation
5. Open venous leg ulcer
6. Not conversant in either English or French
7. Geographic inaccessibility which precludes participation
8. Unwilling or unable to provide signed informed consent
9. Screening (i.e. pre-randomisation) exercise stress test (Bruce Ramp protocol) demonstrating uncontrolled hypertension, ischaemia, or arrhythmia (such patients will be referred for appropriate medical evaluation)

Date of first enrolment
01/03/2006

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Canada

Study participating centre

Sir Mortimer B. Davis Jewish General Hospital
Montreal, Quebec
Canada
H3T 1E2

Sponsor information

Organisation
Sir Mortimer B. Davis Jewish General Hospital (Hôpital Général Juif Sir Mortimer B. Davis) (Canada)

Sponsor details
3755 Côte Ste-Catherine Road
Montreal, Quebec
Canada
H3T 1E2
+1 514 340 8222 ext. 5252
razoulay@jgh.mcgill.ca

Sponsor type
Hospital/treatment centre

Website
http://www.jgh.ca

ROR
https://ror.org/056jjra10

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-82338)

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?
Results article	results	11/01/2011		Yes	No