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Is Nordic Pole Walking (NWP) more effective than normal walking in intermittent claudication patients?

Submission date 20/10/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/10/2011	**Overall study status** Completed	
Last Edited 19/06/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10781

Study information

Scientific Title
Is Nordic Pole Walking more effective than normal walking in improving walking distance in patients with intermittent claudication? A prospective randomised study

Acronym
NWP

Study objectives
Patients with narrowed or blocked arteries in their legs, due to smoking and/or high cholesterol, often suffer from cramping pains in their calf muscles when they walk. This is due to poor blood flow and is called intermittent claudication. Regular exercise can help and supervised classes in a gym provide the most benefit. However, these classes are expensive to run, take time to work and many patients stop coming after a while. Walking with cross country ski (Nordic) poles is a very popular activity in Scandinavia as they improve fitness.

A recent study in Sheffield has found that Nordic Pole Walking immediately helps patients with Intermittent Claudication to walk further with less pain, without any feeling any more tired. This second study will look at whether this immediate benefit is improved by the minimally supervised use of poles over 12 weeks. Patients with intermittent claudication wll be recruited from the vascular outpatient clinics after being provided with information about the study and agreeing to participate. Patients will be randomly allocated to a group who use poles or who receive normal advice to exercise regularly. We will use weekly diaries and pedometers to record the amount of exercise taken. Patients will be invited to attend the gym every month to see how much their walking and fitness has improved.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee Yorkshire and the Humber South Yorkshire ref: 11 /YH/0100

Study design
Interventional, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Cardiovascular disease

Interventions
The only intervention we use is a pair of walking poles..randomly allocated to each patient. Each patient is followed for 12 weeks.

Ankle Brachial Pressure Index (ABPI) measured before and after each visit:
1. Heart Rate
2. Post test heart rate taken every 2 mins until back to resting state.

Research nurse gives patient information sheet. They fill in a tear off strip and return to investigators if they are happy with it. Last visit, base line tests again.Patient diary/pedometer check, weeks 4,8,12.Phone call to arrange visit 0, Investigator phones patient to arrange initial visit for consent and base line data and tests.results notification, Written thanks to patients giving them the results in lay language. Supervision Phonecalls, Weeks 1,2,3,5,6,7,9,10,11.; Visit 0, Base line tests:
Weight, heightm resting heart rate, ABPI using Doppler, max walking distance, claudication distance, Borg pain scale, and Borg RPE.

Consent
Teach NWP technique
Familiarisation with heart rate monitor strap and watch and pedometer.; Walking test with NWP, Same as walking test. Walking tests, Weeks 0,4,8,12. HR, ABPI, CD, MWD, Borg Pain and RPE

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Is the technique of using NPW is more effective in improving walking distance than normal walking?

Measured on each patient at week 0 and 12. At week 4, and 8 we will also be recording the patient's progress using the primary outcome measures, distance walked, level of perceived exertion and level of pain at CD and MWD.

Secondary outcome measures
Compare compliance, the cardiovascular training effect, ABPI and any weight loss.

Measured on each patient at week 0 and 12. At week 4, and 8 we will also be recording the patient's progress using the primary outcome measures, distance walked, level of perceived exertion and level of pain at CD and MWD.

Overall study start date
01/10/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Patients must have stable intermittent claudication due to peripheral arterial disease of more than 6/12 duration of symptoms
2. A resting ABPI of <0.9, which is unsuitable for revascularisation
3. Patient has not had a revascularisation procedure in the last six months
4. Level(s) of disease and unsuitability for revascularisation will have been previously determined by duplex ultrasound and/or magnetic resonance (MR) arteriography.
5. Patients must not have other conditions that could limit their walking distance (e.g. breathlessness or severe osteoarthrosis) or the ability to hold poles
6. Male and female participants
7. Aged between 50 - 100 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Patients with intermittent claudication due to peripheral arterial disease of less than 6/12 duration of symptoms
2. A resting ABPI of >0.9, which is suitable for revascularisation
3. Patient has had a revascularisation procedure in the last six months
4. Level(s) of disease and unsuitability for revascularisation will have been previously determined by duplex ultrasound and/or MR arteriography
5. Patients with other conditions that could limit their walking distance (e.g. breathlessness or severe osteoarthrosis) or problems using their hands which might affect the ability to hold poles

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern General Hospital
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Trust (UK)

Sponsor details
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Private Physiotherapy Educational Foundation (UK)

Funder Name
Sheffield Vascular Research Fund (UK)

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	01/06/2014		Yes	No