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Efficacy of preoperative aquatic resistance training on muscle power and knee symptoms in persons with knee osteoarthritis

Submission date
02/02/2016

Recruitment status
No longer recruiting

Registration date
08/02/2016

Overall study status
Completed

Last Edited
01/02/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis and affects millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, causing stiffness, pain and a reduction in the range of movement. The knee is the most common joint to be affected by OA and in many sufferers, the pain prevents people from moving around leading to muscle weakness and disability. Exercise is considered to be an important part of treatment for knee OA, however when the condition is particularly severe it is difficult to find effective training methods that do not cause the sufferer too much pain. Aquatic resistance training is a type of exercise where a person completes low-impact exercise, such as walking, through water. The natural resistance provided by the water helps to strengthen muscles without putting pressure on the bones and joints. The aim of this study is to find out whether aquatic resistance training can help to strengthen muscles and reduce knee symptoms such as pain and stiffness, in patients suffering from knee OA.

Who can participate?
Adults aged between 50 and 75 with severe OA who have had continuous knee pain for at least 6 months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a 12 week course of aquatic resistance training. The training takes place twice a week in a hospital pool and is experienced by a trained physiotherapist. In the sessions participants where resistance boots (special boots designed to increase resistance) and complete low-impact exercises such as walking through the water. Those in the second group continue to receive standard care and do not take part in any extra training. At the start of the study and then again after 6 and 8 months, participants in both groups complete a number of questionnaires and physical tests in order to assess their muscle strength and knee symptoms.

What are the possible benefits and risks of participating?
All participants benefit from receiving information about their physical performance.

Participants who are in the training group may benefit from improved muscle power and decreased knee symptoms. Risks of taking part are minor but some participants may experience temporary muscle pain after training.

Where is the study run from?
Kymenlaakso Central Hospital (Finland)

When is the study starting and how long is it expected to run for?
January 2009 to October 2013

Who is funding the study?
Kymenlaakso Central Hospital Research Fund (Finland)

Who is the main contact?
Dr Anu Valtonen

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Preoperative aquatic resistance training program to increase muscle power and decrease knee symptoms in persons with knee osteoarthritis: A randomized controlled trial

Acronym
ARISTO

Study objectives
Twelve week preoperative aquatic resistance training intervention will increase muscle power and decrease knee symptoms in persons with end-stage knee osteoarthritis compared to controls receiving standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Kymenlaakso Central Hospital, 21/02/2005, ref: 2/2005/23.2.05

Study design
Randomized controlled trial

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
Knee osteoarthritis

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants receive a 12-week progressive aquatic resistance training intervention that aims to decrease knee symptoms and increase muscle power. Group-based training is conducted in hospital pool and supervised by physiotherapist.

Control group: Participants receive the standard preoperative care, which includes written instructions for training.

Total duration of both preoperative study arms is 12 weeks. Participants are followed up from six to eight months postsurgery.

Intervention Type
Behavioural

Primary outcome measure

1. Muscle power is measured using isokinetic device at baseline, 12 weeks and 6 to 8 months postsurgery
2. Knee symptoms are measured using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) at baseline, 12 weeks and 6 to 8 months postsurgery

Secondary outcome measures
1. Muscle torque is measured using isokinetic device at baseline, 12 weeks and 6 to 8 months postsurgery
2. Thigh muscle cross-sectional area is measured using computed tomography at baseline, 12 weeks and 6 to 8 months postsurgery
3. Walking speed is measured using maximal 10 meter walk test at baseline, 12 weeks and 6 to 8 months postsurgery
4. Ability negotiating stairs is assessed by measured stair ascending and descending times at baseline, 12 weeks and 6 to 8 months postsurgery
5. Mobility and balance is measured using the 8-figure-run test at baseline, 12 weeks and 6 to 8 months postsurgery
6. Ability to get up from the chair is measured using the sit-to-stand test at baseline, 12 weeks and 6 to 8 months postsurgery
7. Mobility and balance is measured using the timed up and go test (TUG) at baseline, 12 weeks and 6 to 8 months postsurgery
8. Quality of life is measured using RAND 36-item health survey 1.0 at baseline, 12 weeks and 6 to 8 months postsurgery

Overall study start date
01/01/2009

Completion date
10/10/2013

Eligibility

Key inclusion criteria
1. Aged between 50 and 75 years
2. Medial knee osteoarthritis according a radiographic grading of Kellgren/Lawrence (K/L) K/L 3 or K/L 4
3. Continuous knee pain lasting at least 6 months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria

1. Lateral knee osteoarthritis
2. Patellofemoral osteoarthritis
3. Rheumatoides arthritis
4. Post-traumatic arthritis
5. Earlier osteotomy
6. Severe cardiovascular disease
7. Dementia
8. Urinary incontinence

Date of first enrolment
01/05/2008

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
Finland

Study participating centre
Kymenlaakso Central Hospital
Kotkantie 41
Kotka
Finland
FIN-48210

Sponsor information

Organisation
University of Jyväskylä

Sponsor details
Department of health sciences
PO Box 35
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Sponsor type
Research organisation

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Research organisation

Funder Name
Kymenlaakso Central Hospital Research Fund

Results and Publications

Publication and dissemination plan
Results of randomised controlled trial with postoperative followup are planned to be published in a peer reviewed journal.

Intention to publish date
30/11/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request