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The effects of resistance training and neuromuscular electrical stimulation in advanced knee osteoarthritis

Submission date
25/05/2009

Recruitment status
No longer recruiting

Registration date
09/07/2009

Overall study status
Completed

Last Edited
18/03/2013

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
The effects of resistance training and neuromuscular electrical stimulation (NMES) in advanced knee osteoarthritis - a comparison of the outcomes of a 6-week program of resistance training versus a 6-week program of NMES versus controls: a prospective, single blinded, randomised, interventional/treatment, efficacy study

Study objectives
How do the two interventions compare objectively (in terms of isometric and isokinetic quadriceps strength, knee functional capacity and quadriceps hypertrophy) and subjectively (in terms of validated surveys of functional health and arthritis)? Do the two modalities induce different changes in gene expression in the muscle atrophy and hypertrophy pathways?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of Cappagh National Orthopaedic Hospital (affiliated with the Royal College of Surgeons in Ireland) provisionally approved on the 30th October 2008 (ref: RBB/10 /2008/20). Full written approval granted by the same committee on the 30th March 2009.

Study design
Single centre interventional treatment single-blind randomised prospective efficacy study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Arm A:
A 6-week home-based exercise program, with particular emphasis on strengthening the quadriceps femoris muscle. The exercises will be adapted to account for individual symptoms and disability severity. Exercises will be performed 3 times per week, with a minimum of 36 hours between each session. Two of the weekly exercise sessions will be supervised by final year Health and Human Performance students of Dublin City University.

Arm B:
A 6-week program of home-based quadriceps femoris neuromuscular electrical stimulation. This will comprise 20 minute sessions 5 times a week, using a portable garment stimulator (Kneehab II, Neurotech, Galway, Ireland). Patients will receive specific instruction from a member of the study team on the application and logbook recording of the stimulator. The device will be applied to the subject's affected thigh, with electrode placement depending on thigh length and girth according to the manufacturer's guidelines. It will be ensured that each subject is competent with garment application, stimulator controls, and completion of the log-diary before commencing training.

Arm C (control group):
Controls will receive standard care. They will undergo all the same functional and clinical evaluations, quadriceps strength assessments, magnetic resonance imaging (MRI) scanning and self-report questionnaires at the same time points as the two intervention groups, but will not undergo muscle biopsies.

Subjects will be assessed at baseline, week 1 (end of familiarisation period), week 7 (end of training period) and week 13 (6 weeks post-training period). Patients in the intervention arms (A and B) will be followed up for 6 weeks post-intervention, and the controls (arm C) will be followed up for the equivalent period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. 36-item Short Form Health Survey (SF-36) and Western Ontario McMaster University Arthritis index (WOMAC) scores, measured at baseline, week 7 and week 13
2. Isometric quadriceps strength (peak torque at 60 degrees of knee flexion) measured bilaterally with a dynamometer, assessed at baseline, week 1 (end of familiarisation period), week 7 (end of training period) and week 13 (6 weeks post-training period)
3. Isokinetic strength at 60 degrees per second in knee extension and flexion measured bilaterally with a dynamometer, assessed at baseline, week 1 (end of familiarisation period), week 7 (end of training period) and week 13 (6 weeks post-training period)
4. Functional testing including a timed 25-metre walking test, a timed stair climbing test and a timed up/down seated test, assessed at baseline, week 1 (end of familiarisation period), week 7 (end of training period) and week 13 (6 weeks post-training period)
5. Quadriceps femoris cross-sectional area on MRI imaging, taken at baseline and week 7

Key secondary outcome(s))
1. Knee flexion and extension limits, both active and passive
2. Height and weight measurements, to determine body mass index
3. Physical activity level
4. Knee pain score immediately before and during all functional and strength testing
5. Vastus lateralis muscle biopsy analysis, taken at baseline and at week 7. Analysis of the muscle biopsy tissue will take place after all participants have completed week 13.
5.1. Key functional and structural protein content including myosin heavy chain
5.2. Gene expression associated with muscle hypertrophy (insulin-like growth factor 1 [IGF-1]) and atrophy (MAFbx and MURF-1)

All secondary outcome measures except the muscle biopsies will be measured at baseline, week 1 (end of familiarisation period), week 7 (end of training period) and week 13 (6 weeks post-training period).

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Male and female patients aged 55 - 75 years
2. Advanced knee osteoarthritis (grade 3 or 4 knee osteoarthritis diagnosed arthroscopically within the last 2 years, or placed on the waiting list for knee replacement surgery with the indication of osteoarthritis within the last 12 months)

3. Ambulatory patients
4. Residing in the Greater Dublin area

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Medical co-morbidities that preclude an exercise program
2. Neurological disorder
3. Implanted electrical device
4. Uncontrolled hypertension
5. Anticoagulant therapy
6. Malignancy
7. Inflammatory arthritis
8. Prior ipsilateral knee replacement surgery or contra-lateral knee replacement surgery within the last 2 years
9. Recent participation in an exercise or strength training program
10. Recent participation in a similar study

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Ireland

Study participating centre
69 Bridgewater Quay
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Sponsor information

Organisation
Cappagh National Orthopaedic Hospital (Ireland)

ROR
https://ror.org/03vc5bf16

Funder(s)

Funder type
University/education

Funder Name
Cappagh National Orthopaedic Hospital (Ireland) - facilities used to perform clinical assessments, percutaneous muscle biopsies and MRI scans

Funder Name
Dublin City University (Ireland) - laboratories and consumables used for the analysis of the muscle samples; dynamometer used for strength testing;

Funder Name
Bio-medical Research (Ireland) - providing neuromuscular stimulators (KNEEHAB®) at no cost. No financial benefit or agreement for same has been made.

Results and Publications

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	03/07/2012		Yes	No