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Optimising patient function following elective Total Hip Replacement (THR) surgery

Submission date
21/02/2011

Recruitment status
No longer recruiting

Registration date
13/05/2011

Overall study status
Completed

Last Edited
04/05/2016

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/WNo01/52

Study information

Scientific Title
The effect of resisted muscle strengthening exercises on patient function following elective Total Hip Replacement (THR) surgery: a prospective, single blind, randomised, controlled trial

Acronym
THR Exercise Study

Study objectives
A home based, largely unsupervised resistance training programme after total hip replacement surgery improves patient function relative to standard physiotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Wales Research Ethics committee, 14/01/2010

Study design
Prospective single-blind randomised 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
Rehabilitation after total hip replacement

Interventions
1. Patients will be randomised to either be in the control group (standard rehabilitation regime) or the intervention group
2. All patients in either group will have assessments pre-operatively and post operatively at 6 weeks, 3 months, 6 months and 1 year
3. The control group will receive routine inpatient and outpatient physiotherapy with the appropriate standard information leaflets provided
4. The intervention group will be shown the training exercises in the pre-assessment clinic and given information sheets
5. On post-operative day 2 (allowing for complications), these exercises will again be shown to them by an experienced physiotherapist

6. On discharge home, they will be seen by a qualified physiotherapist and the program will be adapted to their home environment
7. They will then be reviewed on a weekly basis for 6 weeks where the exercises shall be reviewed and resistance increased

Intervention Type
Behavioural

Primary outcome measure
1. Objective measures of physical function (related to activities of daily living):
1.1. Timed up and go test
1.2. Six minute walk test
1.3. Gait speed, stair climbing performance, and sit to stand score
1.4. Maximal voluntary contraction of quadriceps muscle and hip abductors
The outcomes will be measured pre-operatively and post-operatively at 6 weeks, 6 months and 1 year

Secondary outcome measures
1. Subjective measures of physical function (Oxford Hip Score (OHS) and Western Ontario and McMasters University Osteoarthitis Personal Function (WOMAC PF) subscale
2. Short questionnaire to assess health enhancing physical activity (SQUASH)
3. EuroQoL Quality of life index
4. Objective assessment of physical activity (pedometers for 3 days to assess activity pre-operatively and during the intervention) as well as clinical assessment
5. Recovery locus of control questionnaire, theory of planned behaviour questionnaire, modified zung depression index and modified somatic perception questionnaire will be used to assess motivation to exercise, mood, and perceptions in the recruited population
The outcomes will be measured pre-operatively and post-operatively at 6 weeks, 6 months and 1 year

Overall study start date
01/03/2010

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Patients undergoing primary total hip arthroplasty via a posterior approach which can either be cemented or uncemented
2. The joint affected should be the only severely arthritic joint, with no evidence of inflammatory arthropathy
3. Patient agreement to inclusion is also necessary

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Dementia, or neurological impairment
2. Presence of cancer or muscle wasting illness, severe musculoskeletal impairment, unstable chronic or terminal illness, major depression, and co-morbid disease that contraindicates resistance training

Date of first enrolment
01/03/2010

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Bangor University
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Sponsor information

Organisation
Bangor University (UK)

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Sponsor type
University/education

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Research organisation

Funder Name
North Wales Research Committee (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	21/04/2016		Yes	No