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The effectiveness of adding arm exercise programme following hip replacement in the elderly

Submission date
07/05/2016

Recruitment status
No longer recruiting

Registration date
12/05/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis, which most often affects the knee. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, which can cause stiffness, pain and a reduction in a person's range of movement. Osteoarthritis of the hip (hip OA) is very common, especially in older adults. It can be very painful and if severe, it can make walking very difficult. In these cases, hip replacement surgery (in which the hip joint is replaced using an artificial joint) is the only treatment which is able to help people to regain mobility without suffering from debilitating pain. Many studies have shown that after undergoing hip replacement surgery, exercise is an important part of recovery and the process of regaining mobility. This study is looking at adding an extra set of arm and upper body exercises to the current physical exercise programme used after this type of surgery. The aim of this study is to find out how effective adding the extra exercises to the standard rehabilitation programme compared to the standard rehabilitation programme alone.

Who can participate?
Adults aged 60 and over with severe hip OA who have been admitted for hip replacement surgery at Zvezdara University Hospital.

What does the study involve?
Following surgery, participants are randomly allocated to one of two groups. Those in the first group take part in the standard rehabilitation programme. This involves taking part in 30 minute exercise sessions twice a day, five days a week, for two weeks in hospital, then supervised in the inpatient rehabilitation center (for four weeks) and unsupervised at home (for six weeks) starting the day after surgery. The sessions involve a set of exercises to improve range of motion, muscle strength of the legs, as well as leg function, balance, coordination and gait (way of walking) with weight bearing. Those in the second group also take part in the standard rehabilitation programme but also take part in additional arm and upper body exercises. This comprises of 15 minutes added to each standard exercise session involving physical chair exercises for arm and upper body, with/out resistance and with regular, deep breathing for improvement of patients' posture, flexibility, and range of motion and the muscle strength of

the arms. Participants in both groups undergo a range of assessments at the start of the study and again after 12 weeks in order to find out if their mobility and muscle strength has improved. Participants also complete a questionnaire at these times in order to find out if their quality of life has improved.

What are the possible benefits and risks of participating?
Benefits of taking part in the additional exercises group include improvements to muscle strength, physical ability for daily activities and quality of life. There are no notable risks involved with taking part in this study.

Where is the study run from?
Zvezdara University Hospital (Serbia)

When is the study starting and how long is it expected to run for?
January 2011 to February 2016

Who is funding the study?
University of Belgrade-Faculty of Medicine (Serbia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Belgrade Faculty of Medicine number: 06-6470/50

Study information

Scientific Title
The effectiveness of supplementary arm and upper body exercises to the standard rehabilitation programme following total hip arthroplasty for osteoarthritis in the elderly

Study objectives
Both groups will improve on all outcome measures after a three month exercise programme and the group with the supplementary exercises would have significantly more improvements on all outcome measures compared with the standard exercise group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Boards both at the “Zvezdara” University Hospital and Belgrade Faculty of Medicine, 29/05/2011, ref: 29/V-17

Study design
Prospective single-centre parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Hip osteoarthritis

Interventions
Participants are randomised to one of two groups, and begin their physical rehabilitation one day post-operatively. A randomization sequence is created using a computer-generated list of random nubers block sizes of four.

Control group: The standard rehabilitation programme lasts 30 minutes and consists of exercises to improve joint range of motion and muscle strength lower limbs, function, balance,

coordination and gait with weight bearing from day one and was performed twice a day, five days a week, for two weeks in hospital, after that supervised in inpatient rehabilitation center (for four weeks) and unsupervised at home (for six weeks).

Intervention group: Participants also take part in the standard rehabilitation program but with additional upper limb and body exercises, adding 15 minutes to the sessions. The additional exercises involve additional physical chair exercises for arm and upper body, with/out resistance, in order to improve posture, flexibility and muscle strength and to implement regular, deep breathing.

Participants are assessed at baseline (one day pre-operatively), after the intervention (two weeks postoperatively) and at three months follow-up (12 weeks postoperatively). The first two assessments are done while participants are in hospital and the last one is planned and scheduled as an outpatient check-up.

Intervention Type
Behavioural

Primary outcome measure
Change in the hip function and physical performance of the lower limbs is measured using the Harris Hip score (HHS) at baseline, two weeks and three months postoperatively.

Secondary outcome measures
1. Muscle strength measured by Hand grip strength (HGS) at baseline, two weeks and three months postoperatively
2. Health-related quality of life measured by Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) at baseline, two weeks and three months postoperatively

Added 19/12/2016:
3. Functional status is assessed by the New Mobility Score Modified (NMSMod) at baseline, two weeks and three months postoperatively

Overall study start date
01/01/2011

Completion date
29/02/2016

Eligibility

Key inclusion criteria
1. Aged 60 years and over
2. End stage hip osteoarthritis
3. Admitted to the surgery department of Zvezdara University Hospital

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
The number of recruited patients to 70 accordingly, 35 in each group.

Key exclusion criteria
1. Postoperative complications
2. Patients with cognitive impairment
3. History of congenital dislocation of the hip
4. Bilateral hip disease or inflammatory arthritis
5. Significant neuromuscular disease (e.g. Parkinson’s disease)
6. Lower extremity fractures or paralysis
7. Scheduled to have bilateral joint replacements or had required revision hip replacement

Date of first enrolment
01/01/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Serbia

Study participating centre
Zvezdara University Hospital
Dimitrija Tucovica 161
Belgrade
Serbia
11000

Sponsor information

Organisation
University of Belgrade

Sponsor details
Faculty of Medicine
Doktora Subotica 8
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11000

Sponsor type
University/education

ROR
https://ror.org/02qsmb048

Funder(s)

Funder type
University/education

Funder Name
University of Belgrade - Faculty of Medicine

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017	24/01/2019	Yes	No