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The contribution of a modified physiotherapy exercise program in the overall functional ability of patients with femoral neck fracture after hemiarthroplasty

Submission date
26/10/2014

Recruitment status
No longer recruiting

Registration date
06/11/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Hip fractures are breaks or cracks at the top of the thigh bone (femur) next to the hip joint. They often happen due to a fall, particularly in the elderly as they may fall more often due to medical conditions, poor eyesight or mobility issues. Hip fractures need to be treated by surgery and the affected bone is typically replaced by an artificial hip (arthroplasty). Afterwards, physiotherapy plays a very important part of a patients recovery, helping them to regain their mobility and independence. The physiotherapy program includes exercises that activate muscle groups around the hip and knee joints in order to maximize strength and flexibility of the limb. How well the hip abductors (the muscles that lift the thigh out to the side) work is vital for the proper functioning of the hip joint, as well as overall functional ability of the patient. Here, we want to find out whether and how strengthening of the hip abductor muscles helps patients to recover from a partial hip replacement (hemiarthroplasty) after a hip fracture.

Who can participate?
Adults aged 7085 undergoing hemiarthroplasty after a hip fracture in the 1st Orthopaedic Department of the KAT General Hospital of Attica, Greece.

What does the study involve?
Participants are allocated into one of two groups. Those in group 1 (control group) follow the classical physiotherapeutic protocol. Those in group 2 (research group) follow a modified physiotherapeutic protocol with a focus on strengthening hip abductor muscles. Hip abductor muscle strength and overall functional ability are assessed at 3 months and again at 6 months after surgery.

What are the possible benefits and risks of participating?
Participants are treated by a standardized physiotherapy protocol regardless the modifications to be performed. Given the studys hypothesis, all patients follow a better or equivalent to the classical rehabilitation program. Information obtained from this study may benefit patients

undergoing hemiarthroplasty after a hip fracture in the future. Participation in this study does not increase the likelihood of possible complications after surgery.

Where is the study run from?
1. Laboratory for Research of the Musculoskeletal System (LRMS) of the Faculty of Medicine, School of Health Sciences, National and Kapodistrian University of Athens (Greece)
2. 1st Orthopaedic Department of the KAT General Hospital of Attica (Greece)

When is the study starting and how long is it expected to run for?
April 2012 to December 2015

Who is funding the study?
Investigator initiated and funded (Greece)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2413/21.11.11

Study information

Scientific Title
The effect of modified physiotherapy intervention in postoperative abductors muscles efficiency and functional ability of hip-fractured patients.

Study objectives
The proposed modified physiotherapy intervention may contribute to faster and level best functional recovery compared with the classical postoperative physiotherapy protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. General Assembly of Special Synthesis of Faculty of Medicine, School of Health Sciences, National and Kapodistrian University of Athens, Greece, 21/11/2011, ref: 2413/21.11.11)
2. Scientific Research Council of the KAT General Hospital of Athens, Greece, 30/03/2012, ref:382 /30-03-2012)

Study design
Double-blind, stratified, randomized clinical trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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 protocols in hip-fracture patients.

Interventions
Participants will be divided into 2 groups; control group and research group.
1. The control group will follow the classic physiotherapeutic protocol
2. The research group will follow the modified physiotherapeutic protocol

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in postoperative functional status according to strengthening of hip abductor muscles. This is measured 60 days (3 months) after surgery in Newton (N) with a reliable electronic dynamometer.

Secondary outcome measures
1. At the day of hospital admission evaluation of the prefracture functional status using self-reported measure.
2. Evaluation of postoperative hip abductor muscles strength and functional status using both self-reported (using a questionnaire) and physical performance (Timed Up & Go Test) measures and an objective measure of abductors muscles strength using an electronic dynamometer(3rd and 6th month after surgery)

Overall study start date
06/04/2012

Completion date
14/11/2015

Eligibility

Key inclusion criteria
1. Age 7085 years
2.All participants must be ambulatory and must not have undergone any prior orthopaedic surgery in the fractured or contralateral hip
3. Willing to be assigned to either of the two study groups

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Total target number: 96 participants (each group will include 48 participants)

Total final enrolment
96

Key exclusion criteria
1. Patients who have Body Mass Index (BMI) ≥ 40 or suffering from dementia, chronic respiratory disease, chronic renal failure, heart failure, neurological disorder, undergoing chemotherapy
2. Postoperative will be measuring the length of the lower limbs and excluded patients presenting leg length discrepancies more than 20mm
3. Patients will also be excluded if they present postoperative complications, such as deep vein thrombosis, pulmonary embolism, pneumonia or delirium

Date of first enrolment
06/04/2012

Date of final enrolment

14/11/2015

Locations

Countries of recruitment
Greece

Study participating centre
30 Ouranias Street
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Sponsor information

Organisation
Laboratory for Research of the Musculoskeletal System (LRMS) ,KAT" General Hospital of Athens (Greece)

Sponsor details
Athinas 10, Kifissia
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Greece)

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	01/05/2019	17/12/2020	Yes	No