

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/11/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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 70-85 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?

Sophia Stasi

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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)

Completion date

14/11/2015

Eligibility

Key inclusion criteria

1. Age 70-85 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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Greece)

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	01/05/2019	17/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes