ISRCTN15066737: The exploration of the differences between two surgical approaches in total hip arthroplasty, direct anterior minimal invasive surgery and Hardinge's approach, in obese and non-obese hip osteoarthritic patients

Condition category
Musculoskeletal Diseases
Date applied
07/08/2019
Date assigned
06/09/2019
Last edited
06/09/2019

Prospective/Retrospective
Retrospectively registered
Overall trial status
Ongoing
Recruitment status
Recruiting

Plain English Summary

Background and study aims
In recent years, there has been growing interest in the minimally invasive surgical techniques that are used for the performance of total hip arthroplasty (THA). Over the last decade, direct anterior minimally invasive surgery (DAMIS) has generated scientific interest because of its soft-tissue-preserving nature (intramuscular and internerve technique), combined with the relatively low risk of dislocation. On the other hand, it is well documented that the most common cause of THA is hip osteoarthritis (OA). The main risk factors for developing hip OA are advanced age, a family history of OA, previous hip injury, hip dysplasia and obesity. Specifically, a strong positive correlation has been found between obesity and hip OA (odds ratio ~2). In the literature, several studies indicate that obesity is associated with a higher complication rate after THA and with poorer clinical functional outcomes. Other studies have shown that obese patients do not differ from the non-obese in terms of postoperative outcomes. The data are controversial and further studies need to be performed in obese patients, especially comparative evaluations that compare minimally invasive techniques such as DAMIS with classical surgical interventions such as the Hardinge approach (HA). The HA was chosen because, compared to other classical surgical approaches used in obese patients, it offers good access to the hip joint and achieves a lower rate of dislocation by preserving the joint's posterior stabilizer muscles. The aim of this study is to compare DAMIS and HA in hip OA patients undergoing primary THA, with regard to pain levels, functional status and quality of life. In addition, it will investigate whether these parameters differ between obese and non-obese patients.

Who can participate?
Patients aged over 50 with hip OA who will undergo primary total hip arthroplasty in the 4th and 2nd Orthopaedic Departments of the "KAT" General Hospital of Attica, Athens, Greece.

What does the study involve?
Comparison of the postoperative outcomes of obese and non-obese hip OA patients who have undergone primary THA through DAMIS or HA. Participants are selected from patients who have chosen to be operated by one of the two chief orthopedic surgeons/co-researchers of the present study. One of the orthopedic surgeons performs primary THA using DAMIS, whilst the other prefers the HA. Participants are divided into groups according to both the surgical approach used and their body mass index (BMI: <30 kg/m2 or ≥30 kg/m2). Specifically, the participants are divided into four groups:
Patients who undergo THA with the DAMIS technique:
Group 1: THA-DAMIS /non-obese patients (20 kg/m2 ≤ BMI < 30 kg/m2)
Group 2: THA-DAMIS/obese patients (BMI ≥ 30 kg/m2
Patients who undergo THA with the HA:
Group 3: THA-HA/non-obese patients (20 kg/m2 ≤ BMI < 30 kg/m2)
Group 4: THA-HA/obese patients (BMI ≥ 30 kg/m2)

What are the possible benefits and risks of participating?
Participants will receive a primary total hip arthroplasty as a treatment of choice for their symptomatic hip OA, regardless of the surgical technique to be performed. Information obtained from this study may benefit obese and non-obese hip OA patients undergoing THA in the future. Participation in this study entails no risk of increasing the rate of possible postoperative complications.

Where is the study run from?
Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM), Physiotherapy Department, School of Health and Caring Sciences, University of West Attica, Athens, Greece and the 4th and 2nd Orthopaedic Departments of the "KAT" General Hospital of Attica, Greece.

When is the study starting and how long is it expected to run for?
January 2018 to March 2020

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Dr Sophia Stasi
soniastasi1@gmail.com

Trial website

Contact information

Type

Scientific

Primary contact

Dr Sophia Stasi

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Additional identifiers

EudraCT number

Nil known

ClinicalTrials.gov number

Nil known

Protocol/serial number

Nil known

Study information

Scientific title

Total hip arthroplasty: direct anterior minimal invasive surgery vs Hardinge approach in obese and non-obese hip osteoarthritic patients

Acronym

Study hypothesis

Direct anterior minimal invasive surgery may contribute to a faster and superior functional recovery and a better quality of life compared with the classical Hardinge approach in obese and non-obese hip osteoarthritic patients who undergo total hip arthroplasty.

Ethics approval

Approved 21/02/2019, Ethics Committee of General Hospital of Attica “KAT” (2 Nikis street, 14561, Kifisia, Athens, Greece, Tel: +30 (0)2132086570; Email: agensec@kat-hosp.gr), ref: ΔΣ234/12-03-2019

Study design

Prospective four-group randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Trial setting

Hospitals

Trial type

Treatment

Patient information sheet

Condition

Hip osteoarthritis

Intervention

Total hip arthroplasty (THA) through direct anterior minimal invasive surgery (DAMIS) or Hardinge approach (HA)

Comparison of the postoperative outcomes of obese and non-obese hip OA patients who have undergone primary THA through DAMIS or HA. Participants will be selected from patients who have chosen to be operated by one of the two chief orthopedic surgeons/co-researchers of the present trial. One of the orthopedic surgeons performs primary THA using DAMIS, whilst the other prefers the HA. Participants will be divided into groups according to both the surgical approach used and their body mass index (BMI: <30 kg/m2 or ≥30 kg/m2). Specifically, the participants will be divided into four groups:

Patients who will undergo THA with the DAMIS technique:
Group 1: THA-DAMIS/non-obese patients (20 kg/m2 ≤ BMI < 30 kg/m2)
Group 2: THA-DAMIS/obese patients (BMI ≥ 30 kg/m2)

Patients who will undergo THA with the HA:
Group 3: THA-HA/non-obese patients (20 kg/m2 ≤ BMI < 30 kg/m2)
Group 4: THA-HA/obese patients (BMI ≥ 30 kg/m2)

Intervention type

Procedure/Surgery

Phase

Drug names

Primary outcome measure

Measured preoperatively (baseline), at the end of the 4th and 8th postoperative week:
1. Pain levels evaluated using the Face Pain Scale-Revised (FPS-R)
2. Functionality measured with the Greek version of the Modified Harris Hip Score (MHHS-Gr) and the Timed Up and Go (TUG) test
3. Quality of life evaluated using the Greek version of the International Hip Outcome Tool-12 items (i-HOT12-Gr)

Secondary outcome measures

There are no secondary outcome measures

Overall trial start date

11/01/2018

Overall trial end date

19/03/2020

Reason abandoned (if study stopped)

Eligibility

Participant inclusion criteria

1. Age >50 years
2. Symptomatic and radiographically confirmed hip OA
3. All participants must be ambulatory before surgery
4. Willing to be assigned to the study

Participant type

Patient

Age group

Senior

Gender

Both

Target number of participants

Total target number: 120 participants (Each of the four study groups will include 30 participants)

Participant exclusion criteria

1. Dementia, chronic respiratory disease, chronic renal failure, heart failure, neurological disorder, undergoing chemotherapy, and previous osteotomy or arthroscopy to the involved hip
2. In addition, after enrolment, patients will be excluded if they present postoperative complications that might prevent them from receiving the standardized postoperative physiotherapy intervention

Recruitment start date

19/03/2018

Recruitment end date

19/01/2020

Locations

Countries of recruitment

Greece

Trial participating centre

University of West Attica
Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM) Physiotherapy Department School of Health and Caring Sciences 28 Ag. Spyridonos Street
Egaleo – Attica
12243
Greece

Sponsor information

Organisation

University of West Attica

Sponsor details

Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM)
Physiotherapy Department
School of Health and Caring Sciences
28 Ag. Spyridonos Street
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Greece
+30 (0)210 5385228
lanecasm@uniwa.gr

Sponsor type

University/education

Website

https://lanecasm.uniwa.gr/

Funders

Funder type

Other

Funder name

Investigator initiated and funded

Alternative name(s)

Funding Body Type

Funding Body Subtype

Location

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal, is estimated to take place in March 2021.

IPD sharing statement
Individual participant data collected during the trial will be available after de-identification (text, tables, figures, and appendices), beginning 9 months and ending 36 months following article publication. Access will be granted to researchers who provide a methodologically sound proposal, in order for them to achieve aims in the approved proposal. Proposals should be directed to Dr Sophia Stasi (soniastasi1@gmail.com). To gain access, data requestors will need to sign a data access agreement. After 36 months the data will not be applicable. During recruitment, patients are informed of the purposes of our study. Upon acceptance, and prior to baseline measurements, participants give their written informed consent (document in Greek).

Intention to publish date

01/03/2021

Participant level data

Available on request

Basic results (scientific)

Publication list

Publication citations

Editorial Notes

19/08/2019: Trial's existence confirmed by ethics committee.

Privacy Preference Centre