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Outcomes in patients with osteoarthritis treated with minimally invasive surgery vs a conventional posterior approach in total hip arthroplasty (hip replacement)

Submission date
10/05/2020

Recruitment status
No longer recruiting

Registration date
13/05/2020

Overall study status
Completed

Last Edited
18/05/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A hip replacement (hip arthroplasty) is a common type of surgery where a damaged hip joint is replaced with an artificial one (known as an implant).
The purpose of this study was to compare the functional outcome, perioperative parameters and complications of minimal invasive surgery (SuperPath) to the conventional posterior technique during a follow up period of 6-12 months. These parameters are important, because of rising attention in orthopedic surgery for minimal invasive techniques, despite the ongoing uncertainty about the benefits of MIS.

Who can participate?
Adults over 18 years, with osteoarthritis severe enough to warrant total hip replacement.

What does the study involve?
This study reports the results of a prospective double-blinded randomized controlled trial of patients with primary hip osteoarthritis. The surgery was performed in a single center by one senior orthopaedic chief surgeon, who has elaborate prior experience in hip surgery. Between October 2017 and February 2019, 60 patients who suffered from radiographically confirmed hip osteoarthritis were divided into two groups and treated according to allocation. Treatment consisted of either a minimal invasive surgery approach or a conventional posterior approach. Peri-operative parameters were collected and compared. Questionnaires (harris hip score and Hip disability and osteoarthritis outcome score) to measure functional outcome were taken 6 weeks and up to 6 months postoperative.

What are the possible benefits and risks of participating?
Benefits: contributing to science
Risks: Regular risks of total hip arthroplasty (infection, blood clots, fracture,...)

Where is the study run from?
AZ Rivierenland (Belgium)

When is the study starting and how long is it expected to run for?
October 2017 to August 2019

Who is funding the study?
investigator initiated and funded

Who is the main contact?
Wouter Schroven, wouter.schroven@student.kuleuven.be

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10-2017

Study information

Scientific Title
Functional and radiographic outcomes after Superpath minimally invasive approach vs conventional posterior approach in total hip arthroplasty: a randomized controlled trial

Study objectives
The clinical outcome of the superpath technique is equally good as the clinical outcome of the posterolateral approach

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2017, Ethics committee Az Rivierenland (Kasteelstraat 23, 2880, Bornem, Belgium; +32 (0)3 890 16 64; Dr.Van.Landuyt@sjk.be), ref: none provided

Study design
Prospective single-centered double-blinded randomized 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
Total hip arthroplasty

Interventions
Patients presenting with primary hip osteoarthritis and requiring arthroplasty will be randomized to one of two groups. Randomization will be done using a random number generator and sealed envelopes. Patients will not be aware of which type of approach they will receive.
Group 1 will receive the supercapsular percutaneously-assisted total hip surgery SuperPath), a minimally invasive approach.
Group 2 will be treated with a conventional posterior approach (Moore).
Prior to surgery, every patient will be broadly informed about the course of the study, the possible risks and the right to withdraw at any moment.
Harris hip score and Hip disability and osteoarthritis outcome score will be examined pre-operative, 6 weeks postoperative and up to 6 months postoperative. Perioperative parameters (Hb, operation time, length of stay, NRS-score) will also be investigated.
One day after surgery, a routine X-ray will be taken to measure prosthesis positioning. During data collection, the investigators will be blinded for the type of surgery that was administered.

Intervention Type
Procedure/Surgery

Primary outcome measure
Harris hip score and Hip disability and osteoarthritis outcome score at baseline, 6 weeks and up to 6 months postoperatively

Secondary outcome measures
1. Radiograpic prosthesis positioning (cup abduction angle, stem alignment) measured using X-ray one day after operation
2. Perioperative parameters (Hb, transfusion rate, length of stay, NRS score, operation time) at the time of operation

Overall study start date
01/10/2017

Completion date
01/08/2019

Eligibility

Key inclusion criteria
Symptomatic primary osteoarthritis severe enough to warrant total hip arthroplasty

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
1. Femoral neck fracture
2. Acetabulum fracture

Date of first enrolment
15/10/2017

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Belgium

Study participating centre
AZ Rivierenland
Kasteelstraat 23
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Sponsor information

Organisation
AZ Rivierenland

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Sponsor type
Hospital/treatment centre

Website
https://www.azrivierenland.be

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
The manuscript is intended to be published in a peer reviewed journal. The trial results, as well as an overview of the statistical analysis, will be published in the journal.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Wouter Schroven, Schrovenwouter@hotmail.com, all data relevant for research documented available from 11/05/2020. The data is documented in an Excel-file and available upon request. Participants were informed and consent was given to share anonymized data, framed in professional secrecy.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			18/05/2020	No	No