

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

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| Submission date 10/05/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 13/05/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 18/05/2020 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Radiographic 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

Completion date

01/08/2019

Eligibility

Key inclusion criteria

Symptomatic primary osteoarthritis severe enough to warrant total hip arthroplasty

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
Bornem
Belgium
2880

Sponsor information

Organisation

AZ Rivierenland

Funder(s)

Funder type

Other

Funder Name

investigator initiated and funded

Results and Publications

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 |