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Does leaving the hip joint capsule in place during the implantation of a hip prosthesis lead to better functional results?

Submission date
12/02/2021

Recruitment status
Recruiting

Registration date
12/02/2021

Overall study status
Ongoing

Last Edited
12/03/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Degeneration of hip joint cartilage (osteoarthrosis) can lead to impaired function of the hip with severe pain. It is a common disease, affecting 5%-8% of Western Europe population aged 50 to 70 years. In the initial stage, painkillers can work very well to preserve the function of the hip. There is however no medical treatment that can halt the progression of the disease or regenerate already degenerated cartilage. If conservative treatment is no longer effective, the treatment of choice is to implant a metal prosthesis (Total Hip Arthroplasty, THA). Results are very good, with most of the patients being able to lead a normal, pain-free life without restrictions in their activity. There are different possible surgical techniques to gain access to the hip joint. With the direct anterior approach to the hip (DAA), no tendons have to be detached which later have to heal again. This has the advantage that the patient can put full weight on the leg immediately after the operation. During the operation, an opening in the anterior part of the joint capsule is made. Until now, this flap of the capsule was mostly resected (cut out). During wound healing, a scar forms where the capsule was resected and the hips remains stable. It is known however, that the joint capsule contains a large amount of sensory nerve endings for pain and feedback to the brain for joint position (proprioception). Advances in operative technique and design of implants have made it possible to preserve and reattach the capsular flap. It is suspected that patients with a preserved anterior joint capsule have a more rapid rehabilitation. The aim of this study is to compare the functional outcomes of patients with standard treatment (resection of the capsular flap) with those patients in which the flap was retained and sutured back in place.

Who can participate?
Patients at least 18 years old with primary, end-stage arthrosis of the hip joint and an indication for THA

What does the study involve?
All patients will come to the hospital before the operation for a physical examination (clinical scores). In addition, x-rays of the pelvis and the hip will be taken. The operation will be performed in the same manner in all patients. If the flap of the anterior joint capsule can be

retained throughout the operation, it will be randomly decided in which patients the capsule will be resected (group A) and in which patients the capsule will be retained and sutured back in place (group B). After the operation, all patients will be allowed full weight-bearing. All patients will come back to the hospital at 6 weeks, 12 weeks and 1 year after the operation for a physical and radiographic examination. Measurements will be taken of hip joint function, muscle strength and range of motion.

What are the possible benefits and risks for participating?
There are no specific benefits or risks in participating in the study. Preservation of the hip joint capsule does not result in any risk for the patient. The usual examinations will be performed before and after the operation in both groups. Participation in the study will not affect the waiting time for surgery.

Where is the study run from?
Kantonsspital Aarau (Switzerland)

When is the study starting and how long is it expected to run for?
December 2020 to December 2027

Who is funding the study?
Kantonsspital Aarau (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
2020-02567

Study information

Scientific Title
Comparison of clinical outcome with or without retention of the joint capsule in total hip arthroplasty for treatment of end-stage arthritis

Study objectives
Preservation of the anterior hip joint capsule in total hip arthroplasty via the direct anterior approach maintains postoperative proprioception and improves clinical scores compared to the standard procedure with resection of the anterior capsule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Conditionally approved 07/12/2020, pending revised application, Swiss ethics committee on research involving humans, Nordwest- und Zentralschweiz (Hebelstrasse 53, 4056 Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: 2020-02567

Primary study design
Interventional

Study design
Single-center interventional single-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End-stage osteoarthritis of the hip joint

Interventions
Radiographic examinations of the hip joint will be performed according to the standard procedures for total hip arthroplasty (conventional ap pelvis view and hip cross-table lateral view for pre-operative diagnosis and planning and postoperative evaluation of implant positioning and stability). During standard total hip replacement via the direct anterior approach, the hip joint capsule is incised to access the joint. Feasibility of preservation of the anterior capsule is assessed upon closure. In the study group the anterior capsule will be preserved and reattached, in the control group the anterior capsule will be excised and discharged. Group assignment is not made until the very last moment before closure to ensure that the selection does not affect the main surgery (THA). To avoid observer bias, the person performing the physical testing is unaware of the surgical method.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Proprioceptive function of the hip is measured as the ability of the patient to accurately control joint motion: deviations to reproduce a given position of the leg in space are measured in degrees at baseline, 6 and 12 weeks

Key secondary outcome(s)
1. Functional outcome measured using Harris Hip Score (HHS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Merle d'Aubigné and Postel Score (MdA), Hip disability and Osteoarthritis Outcome Score (HOOS) at baseline, 6 weeks, 12 weeks, 12 months
2. Evaluation of component placement measured using conventional ap pelvis x-ray at 2 days, 6 weeks and 12 months
3. Infection rate and rate of dislocations measured using patient history at 12 months

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. End-stage primary osteoarthritis
2. Age 18 years and older
3. Indication for total hip arthroplasty
4. Direct anterior approach
5. Use of standard implants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Secondary causes of osteoarthritis (e.g. fracture, dysplasia, deformities etc)
2. Prior surgery to the hip joint
3. Inability to follow the procedures of the study, e.g. due to language problems, psychological disorders, dementia, etc.
4. Patients with mental disorders or medical conditions with disturbance of balance, rendering them unable to participate in the physical tests
5. Lack of written consent or refusal to participate
6. Pregnant or lactating women
7. Use of revision implants
8. Contraindications for the use of direct anterior approach (severe obesity, infections or injury to the skin anterior to the hip)
9. Contralateral total hip arthroplasty within the last 12 months
10. Hip joint capsule that cannot be retained for medical or technical reasons until after final positioning of the implants

Date of first enrolment
01/06/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
Kantonsspital Aarau
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Sponsor information

Organisation
Kantonsspital Aarau

ROR
https://ror.org/056tb3809

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Kantonsspital Aarau

Funder Name
Orthopaedic Department Kantonsspital Aarau Research Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available