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Evaluate the effect of posterolateral approach (PLA) in reducing surgical trauma and postoperative inflammatory stress

Submission date
03/09/2024

Recruitment status
No longer recruiting

Registration date
14/09/2024

Overall study status
Completed

Last Edited
13/09/2024

Condition category
Musculoskeletal Diseases

[ ] 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
Currently, there are limited comprehensive results, particularly in understanding how different surgical approaches, such as the posterolateral approach (PLA) and direct anterior approach (DAA), influence deep vein thrombosis (DVT) risk. This study will explore the therapeutic effect of mini-incision total hip arthroplasty (THA) through the PLA, and further analyze the related factors affecting postoperative DVT.

Who can participate?
Patients with osteonecrosis of the femoral head (ONFH) who meet the surgical indications for THA

What does the study involve?
Participants will be randomly allocated into a study group and a control group. The study group will undergo minimally invasive surgery via the PLA and the control group will undergo surgery via the DAA. Incision length, operation time, and intraoperative and postoperative blood transfusion will be recorded. Patients' pain and hip function will be assessed using a scale and a special surgical hospital score.

What are the possible benefits and risks of participating?
Mini-incision THA through the PLA causes less trauma to ONFH patients, which can reduce the occurrence of postoperative inflammatory stress injury. The risks of anesthesia, the risk of bleeding or infection during surgery, and the risk of prosthesis discomfort or loosening and displacement after surgery.

Where is the study run from?
The First Affiliated Hospital of Ningbo University, China

When is the study starting and how long is it expected to run for?
March 2022 to August 2023

Who is funding the study?
1. The Medical Health Science and Technology Project of Zhejiang Province
2. The Traditional Chinese Medicine Technology Project of Zhejiang Province

Who is the main contact?
Yiping Li, Department of Joint Surgery, the First Affiliated Hospital of Ningbo University, liyiping_yp@126.com

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Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
The Medical Health Science and Technology Project of Zhejiang Province (2022KY307), The Traditional Chinese Medicine Technology Project of Zhejiang Province (2023ZL154)

Study information

Scientific Title
Postoperative inflammatory stress in small incision total hip arthroplasty with posterior lateral approach

Study objectives
Mini-incision total hip arthroplasty (THA) via the posterolateral approach (PLA) results in less surgical trauma and reduced postoperative inflammatory stress compared to the direct anterior approach (DAA)

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 07/08/2024, Ethics Committee of The First Affiliated Hospital of Ningbo University (No.59 Liuting Street, Haishu District, Ningbo, 315010, China; +86 0574-87085233; master@nbdyyy.com), ref: 2024-167RS-01

Study design
Single-center interventional double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Evaluation after small incision total hip arthroplasty with posterior lateral approach

Interventions
The sample size was calculated based on a power analysis to detect a significant difference in postoperative inflammatory stress injury, with an expected effect size of 0.5, a power of 0.8, and a significance level of 0.05. Patients were randomly assigned to either the research group or the control group using a computer-generated randomization sequence to ensure unbiased allocation.

Control Group: The patient will be placed in a supine position, with the surgical approach using the anterior superior iliac spine, fibular head, and greater trochanter as landmarks. The skin incision will begin at a distance of 2 cm from the anterior superior iliac spine and 2 cm from the lateral side, with a 6-10 cm incision being made in the direction of the fibular head. The midpoint of the incision will be flush with the apex of the greater tuberosity. The subcutaneous fat will then be cut to expose the tensor fasciae latae. The gap between the tensor fasciae latae, sartorius muscle, and rectus femoris will be bluntly separated, and the lateral femoral circumflex artery will be cut and ligated. Subsequently, the iliopsoas muscle will be separated and exposed, and the iliopsoas muscle membrane will be incised to reveal the anterior capsule. A V-shaped incision will be made to expose the femoral neck. The lower limb will then be towed, the femoral head will be removed, and traction will be relaxed to expose the bony acetabulum. Following this, the ligamentum teres will be excised, revealing the base of the fossa ovale as a marker of the inner wall of the acetabulum. After filing and processing with an acetabular reamer, the corresponding prosthesis will be selected for placement, with two screws being placed in the posterior upper part of the acetabulum to prevent rotation. Finally, the acetabular lining will be placed.

Research Group: The patient will be placed in a lateral position, and surgical incisions will be made towards the distal and proximal ends, curving towards the posterior superior iliac spine, with the patient's greater trochanter as the center. Care will be taken to ensure that 70% of the surgical incision length is at the distal end of the greater trochanter vertex, and 30% is at the proximal position. After the incision is made step by step, the fascia lata will be treated with undermining dissection for 5-10 cm to expand the exposure range. The sciatic nerve will be protected by a long retractor, and the gluteus minimus will be separated from the joint capsule along the upper edge of the piriformis with a Cobb stripper, noting that the piriformis and symphysis tendons will be cut along the piriformis fossa. The capsule will then be cut along the superior border of the piriformis. After posterior dislocation of the hip joint, the lesser trochanter will be exposed, and the femoral neck osteotomy line will be marked before osteotomy to remove the femoral head. Next, the acetabulum will be exposed with an acetabular retractor, and the remaining articular cartilage in the acetabulum will be scraped off with an acetabular reamer. The affected limb will be internally rotated and flexed at an angle of 90° so that the stump of the femoral neck is fully exposed to the outside of the surgical incision. The femoral neck stump will then be fenestrated and reamed to a suitable size with a medullary cavity file, after which prosthesis implantation and reduction will be performed. After the implants are placed in both groups, joint mobility and the length of the legs will be checked, the drainage tube will be indwelled, and the incision will be closed layer by layer.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Pain measured using a Visual Analogue Scale (VAS) before surgery, 1 week after surgery, and one month after surgery
2. Hip function measured using the Hospital for Special Surgery (HSS) score before surgery, 1 week after surgery, and one month after surgery
3. The white blood cell count (WBC), neutrophil-lymphocyte ratio (NLR), and macrophages (mø) measured using an automatic blood cell analyzer (Model: Sysmex XN-1000, Sysmex Corporation, Kobe, Japan). High-sensitivity C-reactive protein (hs-CRP) levels measured with a high-sensitivity immunoturbidimetric assay using the Cobas c 702 module (Roche Diagnostics, Basel, Switzerland). Interleukin-6 (IL-6) measured by enzyme-linked immunosorbent assay (ELISA) using kits ordered from Beijing Xingyi Yachuang Biotechnology Co., Ltd., with readings obtained using the Bio-Rad iMark microplate reader (Bio-Rad Laboratories, Hercules, CA, USA). All measurements were taken 1 week after surgery.
4. Deep Vein Thrombosis (DVT), with DVT diagnostic criteria: swelling, pigmentation, pain in the affected area, weak or no venous blood flow signal on ultrasonography, extremely low venous lumen echo, and irregular pulse Doppler spectrum measured using data collected from patient medical records one month after surgery

Secondary outcome measures
The following secondary outcome measure variables will be collected using patient medical notes after surgery:
1. Incision length
2. Operation time
3. Intraoperative and postoperative blood transfusion

Overall study start date
16/03/2022

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Meet the osteonecrosis of femoral head (ONFH) diagnostic criteria confirmed by the participating hospital
2. Meet the surgical indications for total hip arthroplasty (THA) and scheduled to be operated in the participating hospital with complete medical records
3. Normal preoperative examinations

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
69

Total final enrolment
69

Key exclusion criteria
1. Malignant tumor
2. Coagulation dysfunction
3. Immune deficiency
4. Serious dysfunction of organs such as the heart, brain, liver, and kidneys
4. Mental illness, abnormal intelligence, or inability to communicate normally

Date of first enrolment
02/04/2022

Date of final enrolment
25/08/2023

Locations

Countries of recruitment
China

Study participating centre
First Affiliated Hospital of Ningbo University
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Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Not defined

Funder Name
Medical Science and Technology Project of Zhejiang Province

Alternative Name(s)
Zhejiang Provincial Medical and Healthy Science and Technology Projects, Zhejiang Provincial Medical and Health Science and Technology Projects, Medical and Health Technology Projects of Zhejiang province, Medical and Health Science and Technology Project of Zhejiang Province, Zhejiang Province Medical Science and Technology Project, ,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
Traditional Chinese Medicine Technology Project of Zhejiang Province

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available from the corresponding author, Yiping Li, liyiping_yp@126.com, upon reasonable request.

IPD sharing plan summary
Available on request