A Single Center Prospective Controlled Study of Direct Anterior Approach and Posterior Lateral Approach in the Treatment of Femoral Neck Fractures in Elderly Patients

Team leader unit: Fujian Provincial Hospital

Project leader: Xu Wei

Responsible department: emergency surgery department

Contact number: 13959116868

Participants: Fujian Provincial Hospital

Study years: February 2023 - August 2024

Informed Consent Form · Informed Notification page

Dear patient:

The doctor has confirmed you as. We will invite you to participate in a study, which is a clinical prospective project. The study protocol has been reviewed by the ethics committee for the clinical study.

Before you decide whether to participate in this study, please read the following as carefully as possible. It can help you understand the study and why it was conducted, the procedures and duration of the study, the benefits, risks and discomfort you may have had after participating in the study. If you wish, you can also discuss it with your relatives and friends, or ask a doctor to explain it to help you make a decision.

1 Research background and study objectives

1.1 Disease burden and the current status of the treatment

Femoral neck fracture is a common fracture type in the elderly, and its high disability rate and high mortality rate make it a fatal killer threatening to the life and health of the elderly. Surgery is the main treatment of femoral neck fracture in the elderly patients. Traditional femoral neck fracture in elderly patients mostly adopts the posterolateral approach (PLA) hemihip arthroplasty under spinal anesthesia, and the direct anterior approach (DAA) emerging in recent years can also be used as an option for the treatment of femoral neck fracture in elderly patients. However, due to the long learning curve of DAA, the operation is difficult, and whether this operation can be used as an effective way of femoral neck fracture in elderly patients still needs further study.

1.2 Purpose of this study

To explore the feasibility and efficacy of supine direct anterior approach (DAA) hemiarthroplasty for femoral neck fracture in advanced elderly patients.

1.3 Study participants and the number of expected participants

Unit: Emergency trauma and Orthopedics department of Fujian Provincial Hospital

Estimated number of included participants: 60 participants

2 Who should not take part in the study

① Bilateral femoral neck fracture; ② patients with pathological fracture; ③ with hip dysplasia and rheumatoid osteoarthritis; ④ with systemic or surgical site local infection or inflammatory reaction; ⑤ with other lower limb fractures or severe injuries to other

parts of the body; ⑥ with previous history of hip surgery.

3 What will you need to do if you participate in the study?

3.1 Before you are enrolled in the study, the doctor will ask and record your medical history, and evaluate the patients condition. If the inclusion criteria are met and you voluntarily participate in the study, an informed consent form will be signed. If you are unwilling to participate in the study, it will not cause a bias or influence on your medical care.

3.2 If you volunteer to participate in the study, you will follow the following steps:

After the subject was admitted, the admission routine examination was completed, and the physician arranged for the subject to receive continuous blood glucose monitoring, Holter electrocardiogram, cardiac color ultrasound, human composition analysis and other examinations. The purpose of this study is to collect and store clinical data of elderly patients with femoral neck fracture. General clinical data include gender, age, BMI, fracture classification (Garden, Pauwels, anatomical site classification), comorbidities and preoperative ASA score. The main surgical outcomes included postoperative VAS pain score and hip function Harris score; the secondary outcomes included operative time, intraoperative blood loss and blood transfusion, preoperative and postoperative CK, HB values, hospital days, postoperative complications, and mortality.

3.3 Other matters requiring your cooperation

It is possible that new information about the research methods will emerge during the research project. If new information appears, your study doctor will inform you and discuss with you about your willingness to participate in this study. If you decide to continue your participation in the study, you may be asked to sign a new informed consent form. During the follow-up phase, the doctor may know your situation by telephone, outpatient follow-up, etc.

4 Possible benefits of participation in the study

Participation in this study may timely assess your disease condition and guide your follow-up treatment, but it cannot be guaranteed. You will not receive any form of direct financial benefit from this study.

5 Possible adverse reactions, risks and discomfort, and inconvenience of participating

in the study

If you experience any discomfort, new change or unexpected condition, during the study, inform your doctor and he / she will make a judgment and give appropriate medical treatment.

6 Related fees

The cost of X-ray and CT and operation-related examinations participating in this study shall be paid in accordance with the hospitalization charge process; but the costs of subsequent data collection and analysis shall be borne by the hospital.

During the study, the doctor will do their best to prevent and treat possible injuries due to this study. If an adverse event occurs in a clinical study, the medical expert committee will identify if it is related to the study. The Sponsor will provide corresponding treatment costs and financial compensation for the damage related to the study in accordance with relevant regulations.

7 Confidentiality of personal information

Any information and data obtained during the course of your study will be kept strictly confidential. Your results will be identified by study number / number rather than your name, and information that will identify you will not be disclosed to members of the study team unless you with your permission. No public report on the results of this study will disclose your personal identity. We will make every effort to protect the privacy of your personal medical information as permitted by law.

According to medical research ethics, in addition to personal privacy information, research data will be available for public inquiry and sharing, and inquiry and sharing will be limited to network-based electronic databases, ensuring that any personal privacy information will not be leaked.

8 How do you get more information?

You can ask any questions about this study at any time and answer them accordingly. Your doctor will promptly notify you if there is any important new information during the study that may affect your willingness to continue participating in the study.

9 You can voluntarily choose to participate in the study and withdraw from the study

Whether you will participate in the study is entirely dependent on your wishes. You

may refuse to participate in the study or withdraw from the study at any time during the study, which will not affect your relationship with your doctor or the loss of your medical or other benefits.

For your best interest, your doctor or investigator may suspend you at any time during the course of the study.

10 What should I do right now?

Whether or not to participate in this study is up to you (and your family members).

Ask your doctor any questions before you make your decision to participate in the study.

Thank you for reading the above materials. If you decide to participate in this study, please tell your doctor that he / she will serve you

Arrange all matters related to research. Please keep this information.

Informed consent. Consent signature page

Clinical Study Project Name: A single-center prospective controlled study of direct anterior versus posterolateral approaches for the treatment of femoral neck fractures in advanced elderly patients

Project undertaking unit: Fujian Provincial Hospital

Subject cooperation unit: None

Project task book No.: No

Consent statement

I have read the above introduction to this study and have the opportunity to discuss and ask questions about this study. All the questions I have asked were answered satisfactorily.

I am aware of the risks and benefits that may arise from participating in this study. I know that participation in the study is voluntary, and I confirm that I have enough time to consider this, and I understand that:

- I can always consult my doctor for more information.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and interests will not be affected.

I am also aware that if I withdraw from the study, especially from the study due to medication, if I tell the doctor about the changes in my condition and complete the corresponding physical examination and physical and chemical examination, it will be very beneficial to the whole study.

If I need to take any other medication due to the change in my condition, I will ask my doctor for advice in advance or tell him the truth afterwards.

I agree with the ethics committee of the drug Authority or the sponsor representative to access my study data.

I will obtain a copy of the signed and dated informed consent form.

Finally, I decided to agree to participate in this study, and I promised to follow the doctors advice as much as possible.

Patient signature: _ _ _ _

contact number:

I confirm that the patient has explained the details of this trial, including its authority and possible benefits and risks, and gave him a copy of the signed informed consent form.

Doctors signature: _ _ _ _

The Doctors work phone number: