HIPPI shoulder - Hip-allograft In Proximal humerus fractures versus Plate Implantation alone: a randomized controlled trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON57352

Source
ToetsingOnline

Brief title
HIPPI shoulder

Condition

- Bone and joint therapeutic procedures

Synonym
Proximal humerus fractures (PHF), upper arm/shoulder fracture

Research involving
Human

Sponsors and support

Primary sponsor: Tergooiziekenhuizen

Source(s) of monetary or material Support: Vrienden van Tergooi

Intervention

Keyword: Femoral allograft, Locking plate, Proximal humerus fracture

Outcome measures

Primary outcome

To compare the CMS between patients treated with LCP fixation plus femoral allograft and those treated with LCP fixation alone at 24 months.

Secondary outcome

Secondary study parameters are:

1) Functional and clinical outcomes: Oxford Shoulder Score (OSS), Subjective Shoulder Value (SSV), Numeric Rating Scale (NRS) en de EQ-5DL.

2) Radiological outcomes: Humeral Head Height (HHH), Humeral Neck-Shaft Angle (HNSA), consolidation and secondary displacement of the humeral head.

3) Incidence of complications

Study description

Background summary

Proximal humerus fractures (PHFs) are common osteoporotic fractures in adults and the el-derly, leading to significant disability and reduced quality of life (QoL). Current treatment op-tions for displaced PHFs include locking plate fixation (LCP) and various augmentation tech-niques, but there is no consensus on the optimal treatment. Although, femoral allografts have shown promising results, there is a need for more definitive evidence regarding the utilization of femoral graft augmentation in addition to locking plate fixation in 3- and 4-part PHFs. This study aims to evaluate the effectiveness of using a mushroom-shaped femoral allograft com-bined with LCP fixation compared to LCP fixation alone. We hypothesize that femoral allograft augmentation with LCP

fixation will result in better clinical and functional outcomes than LCP fixation alone at 24 months post-operative.

Study objective

The aim of this RCT is to examine the differences in functional, clinical, and radiological out-comes, between LCP fixation alone and femoral allograft augmentation in addition to LCP. Ultimately, the purpose is to optimize treatment strategies and enhance long-term quality of life outcomes in the management of displaced PHFs.

Study design

This is a single-center, prospective, single-blind, two-armed, parallel-group randomized con-trolled trial (RCT) to be conducted at Tergooi MC. The study will span a maximum of 48 months, including 24 months for patient recruitment and 24 months for follow-up.

All measurements and actions outlined below will be identical for both groups.

1) Patient selection
Patients presenting with a proximal humerus fracture (PHF) at the orthopedics department of Tergooi will be screened based on established inclusion and exclusion criteria. Once they meet these criteria, they will be informed about the study, and written informed consent will be obtained.

2) Randomization and Blinding
Variable, single-blind, blocked randomization will be conducted, stratified by dominant arm, gender (male and female), age, and fracture classification (3-part and 4-part), with an allocation ratio of 1:1, executed via the Castor EDC system.

The study coordinator will inform the surgeon of the assigned treatment for the patients: either LCP fixation alone or femoral allograft augmentation in combination with LCP fixation.

The specialized shoulder physiotherapist conducting the measurements will remain unaware of the patients* treatment groups, and patients will be encouraged not to disclose their treatment group

3) Intervention
The surgery will be performed with same-day admission, allowing patients to return home on the same day.

4) Measurements and follow-up
To test our hypothesis, we will collect data at various follow-up points after

the surgery using standardized measurements and questionnaires. These measurements and questionnaires will be identical for both groups.

The primary and secondary outcome measurements will occur at the following time points:

- Pre-operative baseline measurement (T0)
- 6 weeks post-operative (T1)
- 6 months post-operative (T2)
- 12 months post-operative (T3)
- 24 months post-operative (T4)

Chapter 3 and Chapter 8 of the research protocol, particularly section 8.3, provide a detailed description of the study procedures.

Intervention

This study compares two treatment methods: locking plate fixation (LCP) alone and LCP fixation combined with a femoral allograft. The study is designed with two groups of patients, with each group undergoing one of the mentioned treatments. The patients are randomized in a 1:1 ratio into these groups.

Group 1: the standard of care group, in which only LCP fixation is performed.

Group 2: the intervention group, in which a femoral allograft is added to the LCP fixation. Further visual and detailed explanations regarding these groups can be found in the research protocol, with an extensive description in Chapter 5: Treatment of Subjects.

Study burden and risks

Participation in this study involves no additional burden compared to standard care at Tergooi MC. The study uses routine shoulder function assessments already part of the follow-up protocol, with no extra hospital visits, invasive procedures, or questionnaires required. The risks associated with the investigational treatments are minimal, similar to those observed in previous studies on fibular and femoral allografts. Hospitalization and mortality risks are very low. The procedure aims to improve stability and reduce complications, supported by existing literature.

At Tergooi MC both techniques are already being used in the treatment of proximal humerus fractures: both "plate implantation" (plate with screws) alone and the combination with the "hip allograft" (plate with screws and a graft). Outside the study, the surgeon selects the most appropriate treatment option for the patient. Since both treatments are already standard practice, we do not expect any additional burden or risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients between 40-70 years of age;
Presenting with acute (< 3 weeks) 3- or 4-part PHF according to the Neer-classification criteria;
Be able to understand and communicate in Dutch;
Patient must be competent to make decisions;
Patient is willing and able to complete scheduled study procedure and follow-up appointments up to 24 months;
Provide written IC.

Exclusion criteria

Head-split fractures;
Pathological fractures due to malignancy or metastases;
Individuals diagnosed with dementia or residing in institutional care or other cognitive impairment;
Terminal illness;
Patients with convulsive disorders, collagen diseases, and any other condition that might affect the mobility of the shoulder joint;
Active joint or systemic infection;
History of prior surgery on the same shoulder;
Previous fracture in the same shoulder;
Psychiatric illness that precludes informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-03-2025

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88103.100.24