

# Which head element is more effective for hip fracture implants to prevent implant-related failures? A helical blade or a lag screw

**Submission date**

13/12/2022

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

24/12/2022

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

04/07/2023

**Condition category**

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

## Plain English summary of protocol

### Background and study aims

Early fixation and rehabilitation is the gold standard treatment for intertrochanteric femur fractures. Cement augmentation through perforated head elements has been developed to avoid postoperative complications such as cut-outs or cut-through. The purpose of this study was to compare two head elements in terms of cement distribution using computed tomography (CT) and to examine their initial fixation and clinical outcomes.

### Who can participate?

Adult patients with proximal femur fractures

### What does the study involve?

Internal fixation with a trochanteric fixation nail advanced (TFNA) helical blade cement augmentation is compared with a TFNA lag screw.

### What are the possible benefits and risks of participating?

Possible benefits of participation are frequent clinical evaluation and accurate radiographic investigation of the patient's fractures. Almost no risks are anticipated.

### Where is the study run from?

Shin Kyoto Minami Hospital (Japan)

### When is the study starting and how long is it expected to run for?

September 2020 to August 2022

### Who is funding the study?

Shin Kyoto Minami Hospital (Japan)

### Who is the main contact?

Sadaki Mitsuzawa, [sadaki\\_mitsuzawa@kcho.jp](mailto:sadaki_mitsuzawa@kcho.jp) (Japan)

# Contact information

## Type(s)

Scientific

## Contact name

Dr Sadaki Mitsuzawa

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

Nil known

# Study information

## Scientific Title

Which head element is more effective for cement augmentation of trochanteric fixation nail advanced implants? Helical blade versus lag screw

## Study objectives

The cement position and volume might differ, but the stability and clinical results will be similar between the two groups of elderly patients who had intertrochanteric fractures treated with either a trochanteric fixation nail advanced (TFNA) helical blade or a TFNA lag screw

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 09/02/2021, Ethics Committee of Shin Kyoto Minami Hospital (94 Shichijo Goshonouchi Kitamachi, Shimogyo Ward, Kyoto, 600-8861, Japan; +78 322 3344; minami-

ikyoku@hello.odn.ne.jp), ref: SHIN20-019

2. Approved 17/03/2021, Ethics Committee of Rakuwakai Otowa Hospital (2 Otowa Chinjicho, Yamashina-ku, Kyoto, 607-8062, Japan; +75 593 4111; sandu-ionut@rakuwa.or.jp), ref: RAKUOTO-RIN21-016

## **Study design**

Randomized parallel-assignment study

## **Primary study design**

Interventional

## **Secondary study design**

Randomised parallel trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

No participant information sheet available

## **Health condition(s) or problem(s) studied**

Proximal femur fractures

## **Interventions**

Elderly patients who had intertrochanteric fractures were treated with a trochanteric fixation nail advanced (TFNA) helical blade (Blade group) or a TFNA lag screw (Screw group). In both groups, 4.2 ml of cement was injected under an image intensifier. In both groups, maximum penetration depth was measured. Changes in radiographic parameters and clinical outcomes such as the Parker score and visual analog scale (VAS) were also recorded. Other tests included mechanical stability after surgery, postoperative pain and the early phase of rehabilitation.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Amount of cement distribution measured using CT scan on the day after the surgery

## **Secondary outcome measures**

Clinical outcome measured using a visual analog scale (VAS) scoring and Parker score on postoperative day 14

## **Overall study start date**

01/09/2020

## **Completion date**

30/08/2022

# Eligibility

## Key inclusion criteria

Proximal femur fractures

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

30

## Total final enrolment

29

## Key exclusion criteria

1. Occult fracture detected by magnetic resonance imaging only
2. Pathological fracture
3. Presence of pre-existing implants
4. Multiple trauma or additional fracture that would affect the patient's postoperative rehabilitation

## Date of first enrolment

01/11/2020

## Date of final enrolment

30/04/2021

# Locations

## Countries of recruitment

Japan

## Study participating centre

**Shin Kyoto Minami Hospital**

Minami Nakanochō 8

Kyoto

Japan

600-8876

## Study participating centre

**Rakuwakai Otowa Hospital**  
Otowachinjicho 2  
Kyoto  
Japan  
607-8062

## **Sponsor information**

### **Organisation**

Shin Kyoto Minami Hospital

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Shin Kyoto Minami Hospital

## **Results and Publications**

### **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

### **Intention to publish date**

31/08/2023

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Sadaki Mitsuzawa, sadakimitsuzawa@gmail.com

The type of data that will be shared: Excel file  
Consent from participants is required

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		03/07/2023	04/07/2023	Yes	No