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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

Registration date
24/12/2022

Last Edited
04/07/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 (Japan)

Contact information

Type(s)
Scientific

Contact name
Dr Sadaki Mitsuzawa

ORCID ID
https://orcid.org/0000-0002-6766-5512

Contact details
Minatojimaminamimachi 2-1-1
Kobe
Japan
6500047
+78-302-4321
sadaki_mitsuzawa@kcho.jp

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 Nakanocho 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
94 Shichijo Goshonouchi Kitamachi
Shimogyo-Ku
Kyoto City
Japan
600-8861
+78-322-3344
minami-ikyoku@hello.odn.ne.jp

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?
Results article		03/07/2023	04/07/2023	Yes	No