ISRCTN34394615 https://doi.org/10.1186/ISRCTN34394615

Application of a novel mixed reality navigation technology in the distal interlocking of femoral intramedullary nails

Submission date
17/08/2024

Recruitment status
Recruiting

Registration date
04/09/2024

Overall study status
Ongoing

Last Edited
02/09/2024

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
This study aims to test a new technique involving Mixed Reality (MR) for treating femoral fractures (fractures in the thigh bone). The research team have developed an MR-based three-dimensional spatial positioning technique that may offer advantages over conventional methods such as reducing radiation exposure, providing stereoscopic in-situ visualizations, reducing drilling attempts, and improving hand-eye coordination.

Who can participate?
Adult patients aged 18 to 65 years old with femoral fractures (proximal femoral or femoral shaft fracture) who are undergoing surgery at the Affiliated Kunshan Hospital of Jiangsu University (AKHJU)

What does the study involve?
The study involves two groups: the Mixed Reality Navigation Group (MR) and the Conventional Mechanical Guide Distal Locking Group (Control). The MR group will be treated with the new MR-based technique, while the Control group will undergo the standard treatment. Participants will be randomly assigned to these groups.

What are the possible benefits and risks of participating?
The new MR technique may potentially improve surgical outcomes and reduce complications. However, as with any surgical intervention, there are risks associated with surgery. Participants will receive detailed information about potential benefits and risks before consenting to participate.

Where is the study run from?
The study is run by the Affiliated Kunshan Hospital of Jiangsu University (AKHJU).

When is the study starting and how long is it expected to run for?
July 2023 to July 2026

Who is funding the study?
1. National Natural Science Foundation of China
2. Suzhou City Major Disease Multicenter Clinical Research Project
3. Special Funding for Jiangsu Province Science and Technology Plan (Key Research and Development Program for Social Development)
4. Kunshan Key Research and Development Program Project
5. Gusu Health Talent Plan Scientific Research Project

Who is the main contact?
Dr Ke Lu, sgu8434@sina.com

Contact information

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
National Natural Science Foundation of China: 82172441, Suzhou City Major Disease Multicenter Clinical Research Project: DZXYJ202312, Special Funding for Jiangsu Province Science and Technology Plan: BE2023737 and BE2022718, Kunshan Key Research and Development Program Project: KS2313, Gusu Health Talent Plan Scientific Research Project: GSWS2022109

Study information

Scientific Title

Application of a novel mixed reality navigation technology in distal interlocking of femoral intramedullary nails: a prospective cohort study

Study objectives
The proposed mixed reality (MR)-based three-dimensional spatial positioning technique, compared to conventional approaches, is hypothesized to have several anticipated advantages, including elimination of radiation exposure, provision of stereoscopic in-situ visualizations, reduction in drilling attempts, and enhancement of hand-eye coordination.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/09/2023, Ethics Committee of the Affiliated Kunshan Hospital of Jiangsu University (Affiliated Kunshan Hospital of Jiangsu University, No. 566 East of Qianjin Road, Suzhou, 215300, China; +86 0512 57027807; Ksrmyyiec@163.com), ref: 2023-04-001-H01

Study design
Single-center interventional open-label 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
Femoral fractures (proximal femoral or femoral shaft fracture)

Interventions
This study primarily introduces a novel Mixed Reality (MR) navigation system and single-fluoroscopy calibration for distal interlocking of Intramedullary Nails (IMNs). A retrospective cohort study was conducted from July to December 2023 to assess the efficacy of the MR navigation system. Ten participants with femoral fractures suitable for IMN treatment were recruited. These data were analyzed for initial distal interlocking outcomes, including success rates, and followed up at 1, 2, 3, 6, 9, and 12 months post-operation to evaluate fracture healing and complications.

This is an interventional study involving two groups: the MR navigation system and the Conventional Mechanical Guide Distal Locking Group (Control). Both groups consist of patients with femoral fractures (proximal femoral or femoral shaft fracture) who have undergone surgery at the Affiliated Kunshan Hospital of Jiangsu University (AKHJU).

In the MR group, a total of 40 patients will be treated using an MR-based three-dimensional spatial positioning technique for the distal interlocking holes of femoral intramedullary nails (IMN). This technique allows for automatic and precise calculation of the MR-guided axis in the three-dimensional space.

On the other hand, in the Control group, another set of 40 patients will undergo conventional mechanical guide distal locking, which is the standard treatment for such cases.

The allocation of patients to the two groups is determined by a random number sequence generated by a computer-based random number algorithm, as designed by the study statistician.

Exclusion criteria for the study include severe trauma that precludes safe surgical intervention, unwillingness to participate in the MR navigation-guided surgery, contraindications for surgery, severe comorbid conditions that could impact the outcome or safety of the surgical procedure, and pre-existing conditions that could interfere with the use of MR technology, such as severe visual or cognitive impairments.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
MR-based three-dimensional spatial positioning technique

Primary outcome measure
The initial hit success rate is measured using data collected during the procedures as the number of successful cases on the first attempt to lock the distal holes during the process of using the MR-based three-dimensional spatial positioning technique for the distal interlocking holes of femoral IMNs, divided by the total number of cases attempting this method, at the timepoint immediately following the procedure

Secondary outcome measures
Hit success rate is measured using data collected during the procedures as the number of successful cases when attempting to lock the distal holes using the MR-based three-dimensional spatial positioning technique for the distal interlocking holes of femoral IMNs, divided by the total number of cases in the Mixed Reality Navigation Group (MR), at the timepoint immediately following the procedure

Overall study start date
01/07/2023

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Patients with a primary femoral fracture diagnosis, including proximal femoral fracture or femoral shaft fracture.
2. Suitable for intramedullary nailing (IMN) treatment.
3. Willing to undergo mixed reality (MR) navigation-guided surgery.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Severe trauma that precludes safe surgical intervention
2. Patients unwilling to participate in the MR navigation-guided surgery
3. Patients with contraindications for surgery
4. Individuals with severe comorbid conditions that could impact the outcome or safety of the surgical procedure
5. Patients with pre-existing conditions that could interfere with the use of MR technology, such as severe visual or cognitive impairments

Date of first enrolment
01/07/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
China

Study participating centre
Affiliated Kunshan Hospital of Jiangsu University
No. 566 East of Qianjin Road
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215300

Sponsor information

Organisation
First People's Hospital of Kunshan

Sponsor details
Affiliated Kunshan Hospital of Jiangsu University
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Sponsor type
Hospital/treatment centre

Website
https://www.ksrmyy.org/index.html?eqid=8a03eb04000b51750000000056491524e

ROR
https://ror.org/01kzsq416

Funder(s)

Funder type
Not defined

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Suzhou City Major Disease Multicenter Clinical Research Project

Funder Name
Special Funding for Jiangsu Province Science and Technology Plan

Funder Name
Kunshan Key Research and Development Program Project

Funder Name
Gusu Health Talent Plan Scientific Research Project

Results and Publications

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

Intention to publish date
31/07/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from(Ke Lu sgu8434@sina.com). All de-identified individual participant data, including baseline variables and clinical outcomes, will be shared. These data will be made available within one year after the completion of the study and will remain accessible for at least five years. Consent for data sharing has been obtained from all participants, and the data will be de-identified to protect participant privacy. Currently, there are no known ethical or legal restrictions that would prevent the sharing of these data. Researchers with a reasonable request for data usage are encouraged to submit their requests. All data requests will be reviewed, and requesters may be required to provide a methodologically sound proposal for how they intend to use the data.

IPD sharing plan summary

Available on request