Minimally Invasive Intramedullary Fixation Versus Plate Fixation of Distal Fibular Fractures in Elderly Patients: Study Protocol for a Prospective Multicenter Cohort Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20210

Source
NTR

Brief title
PIN Study (Plate or Intramedullary Nail)

Health condition

fibula, fracture, intramedullary fixation, nail, plate fixation, elderly, prospective cohort

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The total number of postoperative complications, including wound infection, wound healing disorders, implant related complications, deep venous thrombosis, pulmonary embolism, and mortality.

Secondary outcome

Functional scores (including the Olerud-Molander Ankle Score, Parker Mobility Score and Visual Analogue Scale for pain), duration of hospital stay, and number of postoperative hospital visits.

Study description

Background summary

Background:
Intramedullary fixation using a fibular nail is a minimally invasive alternative to conventional plate fixation for operative treatment of distal fibular fractures. This surgical technique has been described to decrease postoperative complications associated with plate fixation and has been suggested to be superior in elderly patients and in patients with compromised soft tissue or severe comorbidities.

Objective:
The aim of this study is to compare the postoperative complications and functional outcomes of intramedullary nail fixation and conventional plate fixation for Lauge-Hansen supination external rotation type 4 or luxation fractures in patients aged 70 years or older.

Design:
This is a prospective multicenter observational cohort study involving two level 2 trauma centers (St Antonius Hospital, Nieuwegein and the Diakonessenhuis, Utrecht). Patients aged 70 years or older with a Lauge-Hansen supination external rotation type 4 or luxation fracture requiring surgical fixation are eligible for inclusion. Patients are treated with either intramedullary nail fixation in the St Antonius Hospital or plate fixation in the Diakonessenhuis according to standard protocol.

Study endpoints:
The primary outcome measure is the total number of postoperative complications, including wound infection, wound healing disorders, implant related complications, deep venous thrombosis, pulmonary embolism, and mortality. Secondary outcome measures are functional scores (including the Olerud-Molander Ankle Score, Parker Mobility Score and Visual Analogue Scale for pain), duration of hospital stay, and number of postoperative hospital visits.

Study objective

Compared to plate fixation, intramedullary fixation allows a minimally invasive technique using smaller incisions and a low-profile implant, causing less postoperative complications by avoiding extensive soft tissue injury, eventually resulting in a decreased number of postoperative complications.

Study design

Intake, 2 weeks, 6 weeks, 3 months and 12 months postoperatively

Intervention

1) Minimally invasive intramedullary fixation using a fibular nail
2) Conventional plate fixation

Contacts

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Eligibility criteria

Inclusion criteria

1) Age 70 years or older
2) Fracture classified as Lauge-Hansen supination external rotation type 4 including fracture associated with luxation of the ankle joint
3) Articular discongruity of >2 mm on X-ray

Exclusion criteria

1) Pathological fractures
2) Severely comminuted fractures (>75%)
3) Presentation delayed by >14 days
4) Polytrauma patients (>2 AIS or >15 ISS with two or more anatomic regions involved)
5) Inoperable patients

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	23-07-2019
Application type:	First submission

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
NTR-new	NL7892
Other	Medical research Ethics Committees United (MEC-U) : W19.025

Study results