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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20210

Bron
Nationaal Trial Register

Verkorte titel
PIN Study (Plate or Intramedullary Nail)

Aandoening

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

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7892
Ander register	Medical research Ethics Committees United (MEC-U) : W19.025

Resultaten