K-wire fixation with direct moBilization versus Open Reposition anD intErnal fixation with direct mobilizAtion in Unstable proXimal phalangeal shaft fractures.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21352

Source
NTR

Brief title
BORDEAUX-Study

Health condition

All adult patients with unstable shaft fractures and fractures with a symptomatic rotational or angular deformity requiring operative treatment.

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Function, pain and disability expressed as change on the Michigan Hand Questionnaire Score (MHQ-DLV) over 3 months

Secondary outcome

Pain, well-being, understanding medical information, total active motion of finger and wrist, patient satisfaction, patient expectation, quality of life, complications, work-absence, cost effectiveness.

Study description

Background summary

Twenty-two percent of hand fractures are fractures of the proximal phalanx (P1). Unstable shaft fractures and fractures with a symptomatic rotational or angular deformity require operative treatment. Multiple techniques have been described in literature. Open reduction and internal fixation (ORIF) or closed reduction and percutaneous K-wire fixation are most commonly used. ORIF leads to more rigid fixation of the bone which guarantees anatomic reduction and direct mobilization. However ORIF is a more invasive and may lead to plate removal, stiffness, longer work-absence and concomitant higher healthcare costs, compared to k-wire fixation. Closed reduction and percutaneous K-wire fixation is a less invasive and cheaper . Usually the PIP and MCP joints are immobilized following K-wire fixation which may lead to stiffness. However some authors support functional treatment though qualitative focused studies are lacking. Therefore, the aim of this study is to compare K-wire fixation with direct mobilization vs ORIF with direct mobilization in patients with unstable shaft fractures and fractures with a symptomatic rotational or angular deformity requiring operative treatment. The primary and secondary outcomes are functional outcome and cost-effectiveness .

Study objective

K-wire fixation followed by direct mobilization leads to better functional outcome, earlier return to work, less re-operations and concomitant lower costs compared to open reposition and internal fixation with direct mobilization in adult patients with an unstable proximal phalangeal shaft fractures and fractures with a symptomatic rotational or angular deformity.

Study design

1: Preparation trial (month 1-2)

2: Inclusion (month 3-20)
3: Follow-up (month 21-33)
4: Data analysis/ Publishing (month 33-36)

Intervention

The intervention group will be treated with K-wire fixation in combination with direct post-operative mobilization, supervised by the hand physiotherapist. Surgery will be performed by a certified trauma surgeon, with experience in hand surgery. Patients will be operated within 14 days after trauma. According to the current standard, antibiotic prophylaxis (Cefazoline, 1000-2000 milligram intravenous) will be administered thirty minutes preoperatively. Closed reduction will be performed using fluoroscopy. When perfect reduction is achieved, K-wires are inserted through the dorsal proximal phalangeal base, crossing the fracture site, and purchasing the cortex of the distal fragment. In the ideal situation the K wires will not cross at the fracture site. Oblique fractures may be treated with parallel K –wires. Post-operatively a compression bandage will be applied for 48 hours. The metacarpal phalangeal joint and the proximal interphalangeal joint will not be immobilized by cast or brace. The K-wires will be removed 4 weeks after surgery.

The control group will be treated with open reduction and internal fixation with plates or lag screws and direct post-operative mobilization, supervised by the hand physiotherapist. Patients will be operated in within 14 days after trauma. According to the current standard, antibiotic prophylaxis (Cefazoline, 1000-2000 milligram intravenous) will be administered thirty minutes preoperatively. The approach may be either a dorsal approach or lateral approach according to the surgeon’s preference. After the fracture site is exposed, the fracture will be reduced. Fixation will be performed with lag-screws or plate fixation depending on surgeons preference. The type and brand of the plate are at discretion of the treating surgeon. Post-operatively a compression bandage will be applied for 48 hours post-operative. The metacarpal phalangeal joint and the proximal interphalangeal joint will not be immobilized by cast or brace. If there are no indications for removing the material, it will remain in place.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients ≥18 years
- Single proximal phalangeal shaft fracture
- Unstable shaft fractures and fractures with a symptomatic rotational or angular deformity requiring operative treatment.

Exclusion criteria

- Stable proximal phalangeal shaft fracture requiring conservative treatment
- Proximal phalangeal shaft fracture of the thumb.
- Open fractures
- Multiple proximal phalangeal fractures
- Patients with impaired hand function prior to injury due to arthrosis/neurological disorders of the upper limb
- Multiple trauma patients (Injury Severity Score (ISS) ≥16)
- Other injuries in the ipsilateral extremity
- Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information as judged by the attending physician
- Patient suffering from disorders of bone metabolism other than osteoporosis (i.e. Paget's disease, renal osteodystrophy, osteomalacia)
- Patients suffering from connective tissue disease or (joint) hyper-flexibility disorders such as Marfan's, Ehler Danlos or other related disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	106
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48485
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7740
CCMO	NL70118.100.19
OMON	NL-OMON48485

Study results