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

Published: 09-01-2020
Last updated: 04-07-2024

To assess the functional outcomes and cost-effectiveness of K-wire fixation followed by direct mobilization versus open reposition and internal fixation with direct mobilization in adult patients with unstable shaft fractures and fractures with a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48485

Source
ToetsingOnline

Brief title
BORDEAUX-study

Condition

- Other condition
- Fractures
- Bone and joint therapeutic procedures

Synonym
broken finger, Finger fracture

Health condition

pees, - ligamentair letsel

Research involving
Human

Sponsors and support

Primary sponsor: Maasziekenhuis
Source(s) of monetary or material Support: Vanuit het Maasstadziekenhuis via een subsidie

Intervention

Keyword: Direct mobilization, K-wire, ORIF, Proximal Phalangeal shaft fractures

Outcome measures

Primary outcome

Function, pain and disability expressed as change during the first 3 months on the Michigan Hand Questionnaire Score (MHQ-DLV) measured at randomization and one, four weeks and 3 months post-operative The MHQ is a validated tool for assessing functional outcome in patients with complaints of the hand5,8. The MHQ is a questionnaire divided in six subscales; overall hand function, activities of daily living (ADLs), pain, work performance, aesthetics and patient satisfaction with hand function. Each subscale has a formula to calculate a score from 0 (severe disability) to 100 (no disability). The final score is a summation of the six individual item-scores divided by six and ranges from 0 (severe disability) to 100 (no disability).

Secondary outcome

- Function, pain and disability expressed on the Michigan Hand Questionnaire Score (MHQ). Therefore MHQ-score will be measured at twelve months post-operative.

- Disability, expressed on Patient Specific Functional and pain Scales (PSFS) at randomization and one, four weeks, three, twelve months post-operative. 9. The PSFS is a list of 3-5 self-chosen activities, scored from 0 (difficult to preform activity) to 10 (no difficulty to preform activity). The final score goes from 0 (severe difficulty) tot 10 (no difficulty) and is a summation of the activity scores divided by the number of activities.
- Health literacy; the ability of an individual to access, understand, and use health-related information and services to make appropriate health decisions, with the Newest Vital Sign- Dutch langue version (NVS-D)10. The NVS-D is a 6-item questionnaire where a score of 4 or more right answers distinguish individuals with adequate versus inadequate health literacy. The NVS-D will be measured ones, an out-patient clinic appointment, preferably at randomization.
- Overall patient satisfaction (of the injury of the hand), on Visual Analogue Satisfaction Scale, scored from 0 (very dissatisfied) to 10 (completely satisfied), measured at randomization and one, four weeks, three, six and twelve months post-operative. - Overall patient satisfaction (of the injury of the hand), on a 5 point scale from -2 (very dissatisfied) to +2 (completely satisfied) measured at randomization and one, four weeks, three, six and twelve months post-operative.
- Patient satisfaction about improvement of function of the finger between the operation and three months with the Visual Analogue Satisfaction Scale, scored from 0 (very dissatisfied) -to 10 (completely satisfied), measured at three months and patient satisfaction about improvement of function of the finger between three months and twelve months with the Visual Analogue Satisfaction

Scale, scored from 0 (very dissatisfied) to 10 (completely satisfied), measured at twelve months.

- Patient satisfaction about improvement of function of the finger between operation and three months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three and patient satisfaction of improvement of function of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Patient satisfaction about improvement of pain of the finger between operation and 3 months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and patient satisfaction of improvement of pain of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Patient satisfaction on improvement of disability of the finger between operation and 3 months on a 5 point scale from -2 (no improvement) to- +2 (completely improved), measured at three months and patient satisfaction on improvement of disability of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Patient satisfaction on aesthetics of the finger over the last 3 months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and patient satisfaction on aesthetics of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely

improved), measured at twelve months.

- Patient satisfaction on work performance over the last 3 months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and patient satisfaction on work performance between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Overall satisfaction of the finger over the last 3 months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at three months and overall satisfaction of the finger between three and twelve months on a 5 point scale from -2 (no improvement) to +2 (completely improved), measured at twelve months.
- Pain as indicated on a Visual Analogue Scale (VAS), where 0 implies no pain and 10 the worst possible pain, measured at randomization and one, four weeks, three, six and twelve months post-operative.
- Patient-expectation; Pre-consultation expectation of the patient on recovery and post-consultation achievement of this expectation. At the first outpatient clinic visit (at randomization) patients will be asked what they expect to achieve in degree of improvement and restriction at a five-point scale; 1. No improvement, full restriction; 2. Slight improvement, serious restriction; 3. Moderate improvement, moderate restriction; 4. Substantial improvement, slight restriction; 5. Complete improvement, no restriction.

At the last outpatient clinic visit (in general at three months) patients will be asked to re-answer this question. Achievement of expectation is expressed as the difference between their answer of the pre-and -post consultation

questions. At twelve months patients will be asked to re-answer this question. Achievement of expectation is expressed as the difference between their answer of the pre consultation question and end of the study question.

- Total active motion (TAM) = Active Range Of Motion of the metacarpal-phalangeal joint, the proximal interphalangeal joint and the distal interphalangeal joint minus any extension deficits. TAM is measured at randomization and one, four weeks and three months post-operative11.

Range of motion (ROM) of the wrist measured on both sides with a handheld goniometer. ROM includes pronation and supination, ulnar and radial deviation and palmar and dorsal flexion of the wrist. ROM is measured at randomization and one, four weeks and three months postoperative.

- Health care costs, productivity losses and out-of-pocket expenses with the adapted Dutch iMTA Medical Consumption Questionnaire and iMTA Productivity Cost Questionnaire (see economic evaluation below), measured at four weeks, three, six and twelve months post-operative.

- Measurement of health status with the EQ-5D-5L at randomization and four weeks, three, six and twelve months post-operative. This questionnaire consists of 5 items, measuring (at 5-point scales) whether patients experience problems, and if so, to what extent with regard to mobility, self-care, daily activities, pain/complaints, and mood.

- Health utility and quality adjusted life-years

- Complications

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

To assess the functional outcomes and cost-effectiveness of K-wire fixation followed by direct mobilization versus open reposition and internal fixation with direct mobilization in adult patients with unstable shaft fractures and fractures with a symptomatic rotational or angular deformity requiring operative treatment.

Study design

Multicentre randomized clinical superiority cost-effectiveness trial comparing K-wire fixation with direct mobilization with ORIF. Study inclusion period 1.5 years

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.

Study burden and risks

Both treatment modalities are standard care. The treatment of choice is currently based on surgeon*s preference. Out-patient clinic visits are within one week (randomization), within 10 days after trauma (operation day) and postoperative; one week(wound control), four weeks (if necessary k-wire removal) and three months.. All visits are standard care in case of operative treatment of proximal phalangeal shaft fractures. During the visits patients will be asked if there are any complaints and/or complications. Physical examination like assessment of the range of motion of the hand and wrist will be executed. Additional to standard care, questionnaires are received at randomization and one, four weeks and three, six and twelve months after operation. Questionnaires can be filled out at home at all times, no additional out-patient clinic visits are necessary for the questionnaires. Patients are asked to fill out MHQ, PSFS, EQ-5D-5L,the Visual Analogue Pain Scale, Visual Analogue Satisfaction scale and 5-point satisfaction scores. Additionally, a questionnaire on any use of health care, health related expenses and absence from work will be administered and patients will be asked to fill out the NVS-D once. Subjects could experience mild discomfort during physical examination and testing, but this will be no different than physical examination during routine follow-up. The burden experienced regarding time spent on questionnaires is difficult to estimate but will most likely <2hours minutes in the total

follow-up duration of this study (1 year).

Contacts

Public
Maasziekenhuis

Maasstadweg 21
Rotterdam 3079 DZ
NL
Scientific
Maasziekenhuis

Maasstadweg 21
Rotterdam 3079 DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a. Population (base)
- All adult patients with unstable shaft fractures and fractures with a symptomatic rotational or angular deformity of the proximal phalanx requiring operative treatment.

b. Inclusion criteria
- Patients >=18 years
- Single proximal phalangeal shaft fracture
- Unstable proximal phalangeal shaft (extra-articular) fracture requiring

operative treatment. Unstable is defined as:
o transverse of oblique fractures with rotational disorders
o scissoring fingers in flexion
o dislocation or re-dislocation (after closed reduction) in a cast:
* >2mm shortening
* >2mm translocation
* >25 degrees angulation
- All comminuted proximal phalangeal fractures
- All proximal phalangeal fractures (regardless exact dislocation measures) resulting in swan neck-deformity, pseudo claw hand, shortening with extension lag.
- Proximal phalangeal fractures with acceptable reduction at the ED, re-dislocated within 1 week after the ED (evaluated by radiograph at the out-patient clinic)

Exclusion criteria

c. Exclusion criteria
- - Stable proximal phalangeal shaft (extra-articular) fracture requiring conservative treatment. Stable is defined as:
o transverse of oblique fractures without rotational disorders
o no scissoring fingers in flexion
o no dislocation or re-dislocation (after closed reduction) in a cast:
* <2mm shortening,
* <2mm translocation
* <25 degrees angulation
- Proximal phalangeal fractures with acceptable reduction at the ED (evaluated with a radiograph at the ED) without re-dislocation within 1 week (evaluated by a radiograph within 1 week at the out-patient clinic) 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2020
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21352
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70118.100.19