Supervised handtherapy versus self-management exercise regimen in conservative treatment of dislocations or hyperextension injury of the vinger

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Self-management exercise regimen are clinically non-inferior compared to supervised hand-therapy. The total costs of self-management exercise regimes are lower.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON29119

Source
NTR

Brief title
PINOT

Condition

- Fractures

Synonym
volar plate injury, PIP dislocation, hyperextension injury of PIP

Health condition

volar plate injury, PIP dislocation, hyperextension injury of PIP

Research involving
Human

Sponsors and support

Primary sponsor: Leading the Change
Source(s) of monetary or material Support: In progress

Intervention

- Movement therapy

Keyword: Handtherapy

Explanation

Outcome measures

Primary outcome

Function, pain and disability expressed as change on the Michigan Hand Questionnaire Score (MHQ) after three months.

Secondary outcome

Pain as indicated on a Visual Analogue Scale (VAS), Well-being with the Patient Specific Functional and pain Scales (PSFS), Understanding medical information with the Newest Vital Sign- Dutch language version (NVS-D), Total active range of motion of the hand (TAM), Patient satisfaction score, Patient expectation, quality of life, complications, work-absence and cost effectiveness and measurement of health status with the EQ-5D-5L.

Study description

Background summary

Approximately 10 000 patients have dorsal dislocations or hyperextension injuries with a volar plate avulsion fracture fragment of the proximal interphalangeal joint in the Netherlands yearly. These types of finger injuries are often caused by ball sports due to hyperextension or axial loading mechanisms. Most of these injuries are stable following reduction. A stable congruent joint following trauma allows for early motion with a dorsal block splint. Arora et al. published a retrospective study on treatment of dorsolateral dislocation of the PIP joint and concluded that early active motion in a dorsal block splint in almost full extension leads to significantly superior results in the range of motion compared to static splinting. A feared complication following hyperextension injuries with volar plate avulsion or PIP dislocations is the development of a flexion contracture. The Dutch guideline committee for hand fractures states that all patients with hyperextension injuries should be referred to a hand therapist within one week. Conversely, there is no evidence that hand-physiotherapy leads to better outcomes than self-management exercise regimen.

Study objective

Self-management exercise regimen are clinically non-inferior compared to supervised hand-therapy. The total costs of self-management exercise regimes are lower.

Study design

MHQ: 1,6 week, 3,12 months

VAS: 1,6 week, 3,6,12 months

PSFS: 1,6 week, 3,12 months

NVS-dlv: 1 week

TAM: 1,6 week 3 months

Patient satisfaction: 1,6 week, 3,6,12 months

Patient expectation: 1 week

Achievement of expectation: 3, 12 months

EQ-5D-5L: 1,6 weeks, 3,6,12 months

CEA: 6 weeks, 3,6,12 months

Intervention

The intervention group will be treated with a well-defined self-management exercise regimen, within 1 week after injury. Additionally, patients will receive a dorsal block splint in zero degrees of flexion for the period of four weeks, starting at the emergency department conform the recommendation by The Dutch Guideline committee for hand fractures.

In the control group, the hand-physiotherapist decides what frequency of follow-up is needed. Hand therapists will be briefed in advance and they will follow a standard protocol for this type of injury. Hand physiotherapy starts within 1 week after injury, according to the Dutch guidelines. Additionally, patients will receive a dorsal block splint in zero degrees of flexion for the period of four weeks, starting at the emergency department conform the recommendation by The Dutch Guideline committee for hand fractures.

Contacts

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Eligibility criteria

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

Inclusion criteria

a. Population (base)

- All adult patients with a PIP hyperextension injury leading to a complete dorsal dislocation, objectified by a doctor at the emergency department or by radiograph at the emergency department. - All adult patients with PIP hyperextension injury leading to a volar plate avulsion, objectified by an avulsion fracture of the proximal volar part of the mid phalanx (< 40% of the joint) on a radiograph at the emergency department.

b. Inclusion criteria

- Patients 18 years and older

- Single PIP hyperextension injuries or dislocation of the fingers

- A stable joint after reduction, assessed by dorsal, volar, and lateral stress on the PIP joint in

extension and 30 degrees of PIP flexion.

- Standard conservative treatment with a dorsal block splint in 0 degrees extension for four weeks.

- Avulsion fracture of the proximal volar part of the mid phalanx (< 40% of the joint)* on a radiograph at the emergency department.

- Standardized Eaton classification: type I,II,IIIa

Exclusion criteria

An avulsion fracture of the PIP joint, >40% of the articular surface

- Re-displacement during digit motion

- An unstable joint after reduction assessed by dorsal, volar, and lateral stress on the PIP joint, requiring operative treatment

- Irreducible dislocations

- Suspicion for interposition of the volar plate

- Operation indication

- Hyperextension injuries of the IP of the thumb

- Multiple PIP hyperextension injuries or dislocation of the fingers

- Patients with impaired hand function prior to injury due to arthrosis/neurological disorders of the upper limb

- Multiple trauma patients (Injury Severity Score (ISS) ¡Ý16)

- 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

- Patients 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 phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2019
Enrollment:	222
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Approved WMO

Date:	24-06-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 55623
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6383
NTR-old	NTR7655
CCMO	NL67400.100.18
OMON	NL-OMON55623

Study results