Continuous Passive Motion and Physical Therapy (CPM) versus Physical Therapy (PT) versus Delayed Physical Therapy (DPT) after Surgical Release for Elbow Contractures; A Prospective Randomized Controlled Trial

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29688

Source
NTR

Brief title
SET-Study

Health condition

Stiff elbow, Capsule release, Rehabilitation, Continuous Passive Motion, Physical Therapy, Randomized Controlled Trial
Stijve elleboog, kapsel verwijdering, nabehandeling, Continuous Passive Motion, fysiotherapie, Randomized Controlled Trial

Sponsors and support

Primary sponsor: Amphia Hospital
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

The primary outcome measure is active and passive ROM (flexion, extension, pronation, supination) of both elbow joints, measured with a universal goniometer, twelve months after surgery.

Secondary outcome

Patient Reported Outcome Measures (PROMs):

The Oxford Elbow Score (OES)

The Mayo Elbow Performance Index (MEPI)

The quick-'Disabilities of Arm, Shoulder and Hand (DASH) score

The Visual Analogue pain Scale in rest and activity (VAS)

The Pain Catastrophizing Scale (PCS)

The SF-36

The WORQ questionnaire for the upper limb

Study description

Background summary

The elbow is prone to stiffness after trauma. To regain functional elbow motion several conservative- and surgical treatment options are available. If conservative treatment fails, an operative release –excision and release of the scarred hypertrophic elbow capsule– of the posttraumatic stiff elbow is often performed. After surgical treatment, several rehab protocols are available, but based on evidence, there is no rehabilitation protocol superior over any of the post-operative treatment options that patients will be assigned to in this study. The following rehab protocols will be compared: 3-day in-hospital regime of CPM with PT versus 3-day in-hospital regime of early motion PT supervised by an upper extremity specialized physical therapist versus outpatient delayed PT supervised by an upper extremity specialized physical therapist from postoperative day 7 as rehabilitation protocol. By conducting this study, we hope to make a statement on the efficacy of costly in-hospital CPM in the

treatment of post-operative rehabilitation for patients undergoing surgery for their posttraumatic stiff elbow. Hereby, unnecessary treatment burden for our patients (prolonged hospital stay, and lengthy CPM sessions) as well as redundant costs for society can be avoided, a more universal Evidence-Based method of treatment can be established and the quality of the care can be improved

Study objective

No difference in range of motion at 12 months follow-up

Study design

Clinical assessment will be performed preoperatively (baseline), during surgery, at day three, at day ten, eight weeks, five months and one year after surgery.

Intervention

Patients that are assigned to the ‘CPM’ group will receive in-hospital CPM in combination with supervised physical therapy the first three days after surgery and supervised physical therapy from day three till day 14 postoperative. Patients that are assigned to the ‘PT’ group will receive in-hospital supervised physical therapy the first three days after surgery and supervised physical therapy from day three till day 14 postoperative. Patients that are assigned to the ‘DPT’ group will receive outpatient physical therapy from postoperative day 7 till 14 and will be discharged from the hospital immediately after surgery. Physical therapy includes both active and passive exercises; moreover patients will be invited to practice at home as well.

Contacts

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Eligibility criteria

Inclusion criteria

Age between 18 and 65 years

Flexion-extension arc of less than 100 degrees or a flexion contracture of more than 30 degrees compared to the contralateral side

Open or arthroscopic surgical treatment received

More than 6 months after trauma

Unsuccessful conservative treatment

Able to read and write in Dutch

Provision of informed consent by patient

Exclusion criteria

Inflammatory diseases (i.e. rheumatoid arthritis, psoriatic arthritis, or reactive arthritis)

Patients with any other elbow pathology (i.e. spastic contracture)

Neck pain or shoulder pain or other chronic widespread pain syndromes

Abnormalities on the X-ray

Wound problems

Inability to cooperate with a structures rehabilitation protocol

Burn-related contractures

A total elbow or interposition arthroplasty (either planned or in place)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2017
Enrollment:	90
Type:	Unknown

Ethics review

Positive opinion

Date:	31-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53066
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5792

Register	ID
NTR-old	NTR6067
CCMO	NL58264.018.16
OMON	NL-OMON53066

Study results