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

Published: 11-08-2016 Last updated: 15-05-2024

Objective of current study is to compare continuous passive motion in combination with physical therapy (CPM) versus early motion supervised physical therapy (PT) versus outpatient delayed supervised physical therapy (DPT) after surgery for...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON53066

Source ToetsingOnline

Brief title CPM vs PT vs DPT for Elbow Contractures

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

Elbow contracture, Stiff elbow

Research involving Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis **Source(s) of monetary or material Support:** Nvt

Intervention

Keyword: CPM, Elbow, Physical Therapy, Release

Outcome measures

Primary outcome

Objective of current study is to compare continuous passive motion with physical therapy (CPM) versus early motion supervised physical therapy (PT) versus outpatient delayed physical therapy (DPT) as rehabilitation protocol after surgery for posttraumatic elbow contractures in a prospective randomized controlled trial, comparing elbow range of motion at 8 weeks, 5 months and 1 year after treatment.

Secondary outcome

Secondary objectives are QALYs and overall patient- (PROMs) and physician-based functional recovery measured with the Mayo Elbow Performance Index (MEPI), Quick-DASH, Oxford Elbow Score (OES) and VAS. These measurements are collected at baseline, 8 weeks, 5 months and 1 year after treatment. Tertiary outcome concerns patient perceived disability according to standardized measurements to evaluate the influence of depression and pain on clinical outcome CES-D (Center for Epidemiologic Studies Depression Scale) as well as the Pain Catastrophizing Scale (PCS) and SF-36. These measurements are collected at baseline, 8 weeks,

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. Conservative treatment includes physical therapy, intra-articular injections with corticosteroids, and a static progressive or dynamic splinting program. If conservative treatment fails, an operative release -excision and release of the scarred hypertrophic elbow capsule- of the posttraumatic stiff elbow is often performed.

The best Evidence-Based rehabilitation protocol for patients after an operative release is unknown, and therefore differs per surgeon, hospital and country to date. Options include early- or delayed motion supervised by a physical therapist, immediate continuous passive motion (CPM), (night) splinting, and a static progressive or dynamic splinting program.

Study objective

Objective of current study is to compare continuous passive motion in combination with physical therapy (CPM) versus early motion supervised physical therapy (PT) versus outpatient delayed supervised physical therapy (DPT) after surgery for posttraumatic elbow contractures in a prospective randomized controlled trial (RCT).

Study design

A multi-centre randomized controlled trial and 12 months follow-up.

Intervention

The following rehab protocols are compared: regime of CPM with PT versus 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.

Study burden and risks

Based on Evidence, there is no rehabilitation protocol superior over any of the other respective post-operative treatment options that patients will be

3 - Continuous Passive Motion and Physical Therapy (CPM) versus Physical Therapy (PT ... 7-05-2025

assigned to in this study. The different treatment options are commonly applied rehabilitation protocols for operative release for posttraumatic elbow stiffness. Main risk is residual stiffness for all treatment options, irrespective of rehab strategy. However, this exposure is part of routine clinical care for posttraumatic elbow stiffness and represents no increased risk.

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.

Contacts

Public Amphia Ziekenhuis

Molengracht 21 Breda 4818 CK NL **Scientific** Amphia Ziekenhuis

Molengracht 21 Breda 4818 CK NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

4 - Continuous Passive Motion and Physical Therapy (CPM) versus Physical Therapy (PT ... 7-05-2025

Inclusion criteria

Open or arthroscopic surgical treatment received Age between 18 and 65 years More than 6 months after trauma Unsuccessful conservative treatment Flexion-extension arc less than 100 degrees

Exclusion criteria

Inflammatory diseases Patients with any other elbow pathology Abnormalities on the X-ray Wound problems

Study design

Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-04-2017
Enrollment:	90
Туре:	Actual

Ethics review

Approved WMO	
Date:	11-08-2016
Application type:	First submission

5 - Continuous Passive Motion and Physical Therapy (CPM) versus Physical Therapy (PT ... 7-05-2025

METC Amsterdam UMC
29-11-2022
Amendment
MEC Academisch Medisch Centrum (Amsterdam)
Kamer G4-214
Postbus 22660
1100 DD Amsterdam
020 566 7389
mecamc@amsterdamumc.nl

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: 29688 Source: NTR Title:

In other registers

Register CCMO OMON ID NL58264.018.16 NL-OMON29688