Functional treatment versus plaster for simple elbow dislocations: a randomized trial

Published: 26-08-2009
Last updated: 15-05-2024

Primary objectiveTo compare the Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire scores, a questionnaire reflecting functional outcome and pain after a pressure bandage (e.g. Tubigrip®) versus plaster treatment in adult...

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

Summary

ID

NL-OMON36458

Source
ToetsingOnline

Brief title
FuncSiE trial

Condition

- Joint disorders

Synonym
elbow luxation, simple elbow dislocation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dislocation, Elbow joint, Multicenter study, Therapy

Outcome measures

Primary outcome

Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) score

Secondary outcome

May Elbow Performance Index (MEPI)

Oxford Elbow Score

Pain level at both sides (VAS)

Range of Motion of the elbow joint at both sides

Rate of secondary interventions

Rate of complication rates

Health-related quality of life: SF-36 andEQ-5D

Radiographic appearance of elbow joint (degenerative changes and ectopic

ossifications)

Costs

Cost-effectiveness

Study description

Background summary

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of elbow dislocations in children and adults is 6.1 per 100.000. Elbow dislocations are classified as simple or complex types. Complex dislocations are associated with fractures of the distal humerus, radial head, ulna, or coronoid process. Simple dislocations are dislocations without fractures.

Different treatment modalities can be appliced after reposition, including plaster immobilisation, surgical treatment of ruptured collateral ligaments, functional treatment, or a combination thereof. When comparing functional treatment versus plaster immobilisation only one RCT was retrieved. Extension and flexion of the elbow did not differ between the groups after one year. Nevertheless, a difference in elbow extension was observed at three months, favouring the patients treated conservatively. Furthermore, when two observational studies were pooled comparing functional treatment with plaster immobilisation, functional treatment showed a statistically significant better result for pain and range of motion.
Although results after functional treatment seem promising, a RCT is needed to further test superiority of either treatment.

Study objective

Primary objective
To compare the Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire scores, a questionnaire reflecting functional outcome and pain after a pressure bandage (e.g. Tubigrip®) versus plaster treatment in adult patients (age 18 years or older), who sustained a simple elbow dislocation.

Secondary objectives
1. To examine the effect of a pressure bandage versus plaster treatment on the degree of sports/music performance (Quick-DASH optional module) in adult patients who sustained a simple elbow dislocation
2. To examine the effect of a pressure bandage versus plaster treatment on the Mayo elbow performance index (MEPI) in adult patients who sustained a simple elbow dislocation
3. To examine the effect of a pressure bandage versus plaster treatment on the Oxford score in adult patients who sustained a simple elbow dislocation
4. To examine the effect of a pressure bandage versus plaster treatment on the level of pain (Visual Analog Scale, VAS) in adult patients who sustained a simple elbow dislocation
5. To examine the effect of a pressure bandage versus plaster treatment on the range of motion (extension, flexion, pro- and supination) of the elbow joint in adult patients who sustained a simple elbow dislocation
6. To examine the effect of a pressure bandage versus plaster treatment on the rate of secondary interventions and complications (redislocations, instability and heterotopic ossifications) in adult patients who sustained a simple elbow dislocation
7. To examine the effect of a pressure bandage versus plaster treatment on health-related quality of life (Short Form-36 (SF-36) and EuroQol-5D (EQ-5D)) in adult patients who sustained a simple elbow dislocation
8. To examine the costs and cost-effectiveness of using a pressure bandage versus plaster treatment in adult patients who sustained a simple elbow dislocation
9. To examine the reliability and validity of the Dutch version of the Oxford

elbow score by comparing the scores with the scores of the Quick-DASH and SF-36 in adult patients treated for elbow dislocations

Study design

Multi-center randomized clinical trial

Intervention

Functional treatment group: The affected arm will be put in a pressure bandage for three weeks. Early active movements within the limits of pain are allowed. Usually by the second day the patients are instructed two exercises by a physical therapist, which are gradually expanded if tolerated.

Plaster group: The affected arm will be put in plaster of Paris for three weeks. At three weeks after dislocation the plaster will be removed and full mobilization (flexion, extension, pro and supination) will be initiated by practicing under supervision of a physical therapist. Physical therapy sessions will be held at regular intervals, preferably 2 times a week during 12 weeks.

Study burden and risks

Both interventions are Standard of Care treatment modalities.

The clinic follow-up visits at t=1, 3 and 6 weeks, and 3, 6 and 12 months are part of Standard of Care. The same holds true for the X-rays for the diagnosis, after reposition and after 1 week and 1 year.

Patients are asked to complete a set of questionnaires at the clinic FU visits mentioned. There are no risks involved in this.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015 CE Rotterdam

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients meeting the following inclusion criteria are eligible for enrolment:
1. Adult men or women aged 18 years and older (with no upper age limit)
2. A simple dislocation of the elbow (i.e., without associated fractures) that can be closed reduced
3. Provision of informed consent by patient.

Exclusion criteria

If any of the following criteria applies, patients will be excluded:
1. Polytraumatized patients
2. Patients with complex, pathological, recurrent or open dislocations
3. Patients with additional traumatic injuries of the affected arm
4. Patients undergoing surgical repair of collateral ligaments of the dislocated elbow joint
5. Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury
6. Retained hardware around the affected elbow
7. History of operations or fractures involving the elbow
8. Patients with rheumatoid arthritis
9. Likely problems, in the judgment of the attending physician or investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded)
10. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information in the judgment of the attending physician.
Exclusion of a patient because of enrolment in another ongoing drug or surgical intervention trial will be left to the discretion of the attending surgeon, on a case-by-case basis.

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:	Recruitment stopped
Start date (anticipated):	28-08-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2009
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

No registrations found.

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

ID: 27801
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL28124.078.09
OMON	NL-OMON27801