Functional treatment versus plaster for Simple Elbow dislocations (FuncSiE): a randomized trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27801

Source
Nationaal Trial Register

Brief title
FuncSiE

Health condition

Simple elbow dislocation

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Department of Surgery-Traumatology
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Mayo Elbow Performance Index (MEPI);

2. Oxford Elbow Score;

3. Pain level (VAS);

4. Range of Motion of the elbow joint;

5. Rate of secondary interventions;

6. Rate of complications;

7. Health-related quality of life (SF-36 and EQ-5D);

8. Radiographic appearance of elbow joint (degenerative changes and ectopic ossifications);

9. Costs;

10. Cost-effectiveness.

Study description

Background summary

BACKGROUND:

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 immobilization, surgical treatment of ruptured collateral ligaments, functional treatment, or a combination thereof. When comparing functional treatment versus plaster immobilization 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, favoring the patients treated conservatively. Furthermore,when two observational studies were pooled comparing functional treatment with plaster immobilization, 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.

AIM:

The primary objective of this RCT is 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 aims are to assess effects on functional outcome, pain, range of motion, rates of complication and secondary interventions, and quality of life in these patients. The costs and cost-effectiveness of both interventions will be determined.

STUDY DESIGN:

Multi-center randomized clinical trial.

POPULATION:

Patients aged 18 years or older with a simple elbow dislocation that can be closed reduced.

INTERVENTIONS:

Functional treatment group: The affected arm will be put in a pressure bandage for up to 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.

ENDPOINTS:

Primary outcome (Quick-DASH) and secondary outcomes (MEPI, Oxford Elbow Score, pain, ROM, secondary intervention rates, complication rates, SF-36, and EQ-5D) will be compared at baseline, at 1, 3 and 6 weeks, and at 3, 6, and 12 months after start of treatment, using both univariate and multivariable analyses. Costs for (in)formal healthcare consumption will be determined for both interventions, Cost-effectiveness will be expressed as cost per quality

of life year (QALY) gained.

Study objective

Functional treatment of a simple elbow dislocation with a pressure bandage (e.g. Tubigrip®) results in improved Quick-DASH scores (reflecting better functional outcome with less pain) compared with plaster. Improved Quick-DASH scores are expected to be noticeable from six weeks after treatment initiation onwards, reflecting a quicker functional recovery for the functional treatment group.

Study design

Baseline, 1 week, 3 weeks, 6 weeks, 3 months, 6 months, 12 months.

Intervention

1. Functional treatment;

2. Plaster treatment.

Contacts

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Eligibility criteria

Inclusion criteria

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 fracture) that can be closed reduced;

3. Provision of informed consent by patient.

Exclusion criteria

1. Polytraumatized patients;

2. Patients with complex, pathological, recurrent or open dislocations;

3. 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 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:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2009
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	24-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36458
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1908
NTR-old	NTR2025
CCMO	NL28124.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36458

Study results

Summary results

De Haan J, Den Hartog D, Tuinebreijer WE, Iordens GIT, Breederveld RS, Bronkhorst MWGA, Bruijninckx MMM, De Vries MR, Dwars BJ, Eygendaal D, Haverlag R, Meylaerts SAG, Mulder JWR, Ponsen KJ, Roerdink WH, Roukema GR, Schipper IB, Schouten MA, Sintenie JB, Sivro S, Van den Brand JGH, Van der Meulen HGWM, Van Thiel TPH, Van Vugt AB, Verleisdonk EJMM, Vroemen JPAM, Waleboer M, Willems WJ, Polinder S, Patka P, Van Lieshout EMM, Schep NWL. Functional treatment versus plaster for simple elbow dislocations (FuncSiE): a randomized trial. BMC Musculoskelet Disord 2010;11:263.