A hinged external fixator for complex elbow dislocations: A prospective cohort study.

No registrations found.

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

Summary

ID

NL-OMON23505

Source
Nationaal Trial Register

Brief title
Elbow Fixator

Health condition

Complex elbow dislocations

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Department of Surgery-Traumatology
Erasmus Medical Center, Medical Ethical Committee (METC)
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. Radiographic healing;

6. Rate of secondary interventions;

7. Rate of complications;

8. Health-related quality of life (SF-36).

Study description

Background summary

BACKGROUND:

The elbow joint is the second most commonly dislocated joint in adults. The annual incidence of elbow dislocations is 6.1 per 100.000. Complex dislocations of the elbow are associated with fractures. The majority of elbow fractures in adults involves the radial head (30%), the olecranon process (20%), or the coronoid process (10-15%). The fundamental goal in the management of fracture dislocation of the elbow is the restoration of the osseous-articular restraints. Therefore, the majority of these complex dislocations is treated with open reposition and internal fixation (ORIF) and/or arthroplasty. Due to ligament disruption, complex elbow dislocations are at risk of persistent instability if not treated adequately. The current postoperativemanagement of instable elbows following ORIF and/or arthroplasty (of the radial head) consists of primary ligament repair and/or a period of plaster immobilization.A period of plaster immobilization after ORIF may result in a limited range of motion of the elbow joint with subsequent stiffness and (major) disability. A hinged external elbow fixator, on the other hand, may provide enough stability to start early mobilization after surgery. This may potentially limit future disability due to restricted motion.

AIM:

The primary aim of this trial is to study the Quick-DASH (Disabilities of the Arm, Shoulder, and Hand) scores, reflecting functional outcome and pain in patients who sustained a complex elbow dislocation and were treated with ORIF and/or arthroplasty and a hinged external fixator.

Secondary aims are to determine functional outcome, pain, range of motion, rates of complication and secondary interventions, time to radiographic healing, and quality of life in these patients.

STUDY DESIGN:

Multi-center cohort study.

POPULATION:

Adult patients (18 years or older) with a complex elbow dislocation, treated with a hinged external fixator to treat persistent instability of the elbow joint following ORIF.

INTERVENTIONS:

External elbow fixating is performed using the Othofix® Elbow Fixator (Orthofix Verona, Italy). After surgery, patients are allowed to use a sling for 2 days to one week. Patients will receive after-treatment following a standardized physical therapy protocol. Extension, flexion and pro- and supination active and passive exercises may be started immediately after surgery if tolerated. After 6 weeks the external fixator will be removed.

ENDPOINTS:

Primary outcome (Quick-DASH) and secondary outcomes (MEPI, Oxford Elbow Score, pain, ROM, secondary intervention rates, complication rates, and quality of life will be monitored at regular intervals over the subsequent 12 months (2 weeks, 6 weeks, 3 months, 6 months and 12 months).

Study objective

A hinged external elbow fixator may provide enough stability to start early mobilization after ORIF and/or arthroplasty (of the radial head) of complex dislocations with residual instability. Our hypothesis is that early mobilization will prevent loss of flexion and extension and will

result in Quick-DASH scores ranging from 45-60, reflecting moderate disabilities, at 1 year.

Study design

Baseline, 2 weeks, 6 weeks, 3 months, 6 months, 12 months.

Intervention

Hinged external fixator.

Contacts

Public
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
P.O. Box 2040
N.W.L. Schep
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
P.O. Box 2040
Rotterdam 3000 CA
The Netherlands
+31-10 7031050
Scientific
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
P.O. Box 2040
N.W.L. Schep
Erasmus MC, dept. of Surgery-Traumatology
Mailbox H-822k
P.O. Box 2040
Rotterdam 3000 CA
The Netherlands
+31-10 7031050

Eligibility criteria

Inclusion criteria

1. Men or women aged 18 years and older (with no upper age limit);

2. Patient with a complex elbow dislocation (i.e., dislocation of the elbow joint, combined with at least a fracture of the radial head, coronoid process, or olecranon);

3. Patient was treated with a hinged external fixator after ORIF and/or arthroplasty due to persistent instability;

4. Provision of informed consent by patient.

Exclusion criteria

1. Patients with distal intra-articular humeral fractures;

2. Patients with additional traumatic injuries of the affected upper limb;

3. Patients who underwent repair of the collateral ligaments and immobilization;

4. Patients with an impaired elbow function (i.e., stiff or painful elbow or neurological disorder of the upper limb) prior to the injury;

5. Retained hardware around the affected elbow;

6. Likely problems, in the judgment of the investigators, with maintaining follow-up (e.g., patients with no fixed address will be excluded);

7. Insufficient comprehension of the Dutch language to understand the 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:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-08-2009
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36547
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1882
NTR-old	NTR1996
CCMO	NL28503.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36547

Study results

Summary results

Schep NWL, De Haan J, Iordens GIT, Tuinebreijer WE, Bronkhorst MWGA, De Vries MR, Goslings JC, Ham SJ, Rhemrev S, Roukema GR, Schipper IB, Sintenie JB, Van der Meulen HGWM, Van Thiel TPH, Van Vugt AB, Verleisdonk EJMM, Vroemen JPAM, Wittich P, Patka P, Van Lieshout EMM, Den Hartog D. A hinged external fixator for complex elbow dislocations: A multicenter prospective cohort study. BMC Muskuloskel Dis 2011;12(1):130.

Iordens GIT, Den Hartog D, Van Lieshout EMM, Tuinebreijer WE, De Haan J, Patka P, Verhofstad MHJ, Schep NWL (on behalf of the Dutch Elbow Collaborative).

Good Functional Recovery of Complex Elbow Dislocations Treated With Hinged External Fixation: A Multicenter Prospective Study.
Clin Orthop Relat Res 2015 Apr;473(4):1451-1461.