

Operative TightRope stabilisation versus conservative treatment for Rockwood type III acromio-clavicular joint dislocation

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To find out whether surgical treatment of acute Rockwood type 3 AC dislocations, by anatomic reconstruction using the arthroscopic TightRope technique, will give a better functional outcome then conservative treatment.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON33728

Source

ToetsingOnline

Brief title

TRACS (TightRope Acromio-Clavicular Stabilisation) study

Condition

- Fractures

Synonym

dislocation, luxation

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acromioclaviculair, dislocation, Rockwood, stabilisation

Outcome measures

Primary outcome

Visual Analogue Scale (VAS) score for pain and activity level

Constant-Murley shoulder score

Disabilities of Arm Shoulder and Hand score (DASH)

Nederlandse Simpele Schouder Test (NSST)

Secondary outcome

-

Study description

Background summary

AC dislocations are often caused by a fall on the shoulder in young active males. The treatment of acute AC dislocations Rockwood type 1 and 2 is conservative. In Rockwood type 4,5 and 6 AC dislocations treatment is surgical. In the case of Rockwood type 3 AC dislocations there's still no evidence based consensus regarding treatment.

Study objective

To find out whether surgical treatment of acute Rockwood type 3 AC dislocations, by anatomic reconstruction using the arthroscopic TightRope technique, will give a better functional outcome then conservative treatment.

Study design

In the study protocol patients with acute AC dislocations of Rockwood type 3 will be prospectively randomised to either conservative treatment or surgical treatment using the arthroscopic TightRope technique.

Intervention

Patients in the intervention group will be treated surgical with the arthroscopic TightRope system.

Study burden and risks

Because the arthroscopic TightRope system is already being used in Rockwood type 4, 5 and 6 AC dislocations, no extra specific operative risks are expected. The general operative risks are wound infection, haematoma formation, nerve injury and redislocation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

AC dislocation Rockwood type III
acute trauma within 6 weeks
age 18 or older
informed consent

Exclusion criteria

age under 18
gleno-humeral instability
fracture
frozen shoulder
previous AC surgery
non compliant by mental state or language barrier

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	01-05-2009
Enrollment:	64
Type:	Anticipated

Ethics review

Approved WMO

Date: 08-06-2009
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.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

No registrations found.

In other registers

Register	ID
CCMO	NL24443.098.09