TightRope AcromioClavicular Study; TRACS.

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23177

Source Nationaal Trial Register

Brief title TRACS

Health condition

Acromioclavicular luxation, TightRope, shoulder instability

Sponsors and support

Primary sponsor: Medical Center Haaglanden, The Hague St Antonius hospital, Nieuwegein Spaarne hospital, Amsterdam

Intervention

Outcome measures

Primary outcome

DASH score 6 months and 1 year.

Secondary outcome

1. VAS painscore;

2. NSST;

3. Constant Murley score.

Study description

Background summary

Acromio-clavicular (AC) dislocation is often caused by a fall on the shoulder in younger patients. The treatment of these acute luxations is still on debate also because differences in seriousness. New artroscopic treatment makes it possible to fixate AC without large surgical procedure. Maybe this intervention makes it possible to receive consensus on treatment of Rockwood fractures.

Study objective

Acute Rockwood type 3 AC-luxations will have a better function after operative treatment with the artroscopic TightRope technique than patients treated conservative.

Study design

Postoperative 6 weeks, 3 months, 6 months and 1 year.

Intervention

- 1. Operative treatment with artroscopic TightRope system;
- 2. Conservative treatment with slinge and physiotherapy.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. AC-dislocation Rockwood type 3 confirmed with CT scan;
- 2. Presentation within 6 weeks after trauma;
- 3. Patients older than 18 years;
- 4. Patients with signed informed consent.

Exclusion criteria

- 1. Age younger than 18 years;
- 2. Glenohumeral instability;
- 3. Other fractures to the shoulder joint;
- 4. Frozen shoulder;
- 5. Earlier attempt to fixate AC;
- 6. Non compliance.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-07-2009
Enrollment:	50
Туре:	Anticipated

Ethics review

Not applicable	
Application type:	

Not applicable

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
NTR-new	NL1682
NTR-old	NTR1783

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Register	ID
Other	METC Medical Center Haaglanden : 09-052
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Jansen JA, Arkel van ERA. Artroscopische stabilisatie van acute acromioclaviculaire luxatie beschrijving van een nieuwe techniek en eerste resultaten. Ned Tijdschrift v Orthopedie Dec 2007, vol 14 (4): 143-47.