Long-term outcome after conservative treatment for Rockwood type I-II injuries

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The purpose of this study is to assess the long-term outcome after conservative therapy for Rockwood type I-II acromioclavicular injuries with regard to subjective and objective functional outcome.

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

Summary

ID

NL-OMON46118

Source
ToetsingOnline

Brief title
LOCTAI

Condition

- Joint disorders

Synonym
"Acromioclavicular injury" or "Collar bone (sub)luxation"

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Stichtingen betreffende financiering wetenschappelijk onderzoek (nader te bepalen).

Intervention

Keyword: AC-injuries, Conservative treatment, Long-term outcome, Rockwood I-II

Outcome measures

Primary outcome

The main study parameter is the functional outcome of the injured shoulder compared to the contralateral shoulder, measured by two patient-reported outcome measures; the DASH and the Nottingham Clavicle Score. In a subgroup of 80 patients two functional outcome scores will be measured; the Constant score and the ASES.

Secondary outcome

AC pressure pain and the cross arm adduction test Range of motion Radiographic displacement Radiographic joint space Radiographic changes: (degenerative changes, ossification of the ligaments, distal clavicular osteolysis) The need for subsequent surgery due to chronic AC-pathology Patient satisfaction Return to sports

Study description

Background summary

Rockwood I-II acromioclavicular joint injuries are generally treated conservatively. Not much literature exists on the long-term outcome, however few studies have shown higher rates of chronic acromioclavicular joint pathology than previously recognized. Patients risk being inadequately informed on possible residual symptoms or the need for subsequent surgery.

Study objective

The purpose of this study is to assess the long-term outcome after conservative therapy for Rockwood type I-II acromioclavicular injuries with regard to

subjective and objective functional outcome.

Study design

This study will be a case series based on retrospective data collection and prospectively measured self-reported outcomes and. A subset of 80 patients will be radiologically and clinically evaluated for current outcomes.

Study burden and risks

All patients will be asked to fill in a digital a questionnaire. The questionnaires will take about 15-30 minutes to complete. 80 patients will be invited for a visit to OLVG for clinical and radiological follow-up. The burden and risk associated with returning to the OLVG for physical examination can be considered low. The risk associated with the making of two radiographs of the shoulder is an exposure of radiation approximately 6 uSv. This amount of radiation is comparable to the radiation exposure the average inhabitant of the Netherlands receives during a day (7uSv) and therefore is regarded a negligible risk. The follow-up activities will be completed in 1.5 hours, including the radiographs.

Contacts

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OLVG

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

To be eligible to participate in this study, patients have to meet all of the following criteria: - currently 18 years or older, - diagnosed with a Rockwood type I-II acromioclavicular injury, - a minimal follow-up of 2 years after AC-injury, - antero-posterior radiographs at the time of presentation, - able to read and write in the Dutch language in order to complete the questionnaires and to sign informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: - previous shoulder injuries (fractures, rotator cuff injuries, shoulder instability) or previous surgery in either the injured or contralateral shoulder at the time of presentation. - additional shoulder injuries (fractures, rotator cuff injuries, shoulder instability) or surgery in either the injured or contralateral shoulder at the time of presentation. - unable to sign informed consent or complete the questionnaires for other reasons than illiteracy in Dutch.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2018
Enrollment:	120

Type:	Actual

Ethics review

Approved WMO Date:	31-10-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL67035.100.18