Clinical outcomes of coracoid fractures

Published: 16-08-2017
Last updated: 12-04-2024

Currently there is little scientific data about the clinical outcomes of the conservative and operative treatment of coracoid fractures. Most of the studies performed are case reports or retrospective studies with a small population. Therefore, we...

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON45319

Source
ToetsingOnline

Brief title
Clinical outcomes of coracoid fractures

Condition

- Fractures

Synonym
Coracoid process, shoulder

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: Stimuleringsfonds

Intervention

Keyword: clinical, Coracoid, fracture, outcomes

Outcome measures

Primary outcome

The Oxford shoulder score at minimal 6 months after treatment.

Secondary outcome

- SF-12 health survey

- Demographic data: sex, weight, height, BMI, age, co-morbidities

- Type of coracoid fracture (Type I or II)

- Associated SSSC injury

- Range of motion

- Presence of consolidation on x-ray

- Complications/Re-operations

Study description

Background summary

The coracoid process, also known as the lighthouse of the shoulder, is a hook-like structure that is part of the scapula. It has three basic functions:
- Serving as a point of attachment for multiple musculotendinous and ligamentous structures
- Providing the glenohumeral joint with anterosuperior stability
- Serving as an integral part of the SSSC (Superior shoulder suspensory complex)
Coracoid fractures are rare whereas the incidence has been assessed between 3% and 13% of all scapular fractures. These constitute 1% of all fractures.

According to Ogawa et al. coracoid fractures can be classified in to two types depending on the location of the fracture. Type I fractures are located posterior from the trapezoid and conacoid ligament. Type II fractures are located on the anterior side of both ligaments. Retrospective study shows that 87% of all conservative treated type II fractures have a good outcome in function and pain.
The SSSC is an imaginary bony/soft tissue ring that is composed of the glenoid process, coracoid process, coracoclavicular ligaments, distal clavicle, AC

joint and the acromial process. Commonly associated injuries are acromioclavicular dislocations, glenoid rim fractures, clavicular fractures and acromial fractures and even scapula fractures.
Type I fractures are often associated with ipsilateral injury to SSSC.
According to Goss there is an increased chance of developing chronic complaints after conservative treatment if there is a double disruption of the SSSC. Oh et al. also reported that an operative treatment gives a better outcome when there were two or more disruptions of the SSSC.

Study objective

Currently there is little scientific data about the clinical outcomes of the conservative and operative treatment of coracoid fractures. Most of the studies performed are case reports or retrospective studies with a small population. Therefore, we want to perform a follow-up study on the clinical outcomes of all the patients with a coracoid fracture who were treated in het Spaarne Gasthuis and Bergman Clinics.

Study design

The researcher will search the database for patients who were treated for a coracoid fracture in the Spaarne Gasthuis Hoofddorp and Bergman Clinics in Naarden. The patients will receive a request letter through mail about the study. After one week the researcher will contact the patient by telephone to determine whether he/she wants to participate. If the patient is willing to participate an appointment will be scheduled to give informed consent. Additionally, the questionnaires will be filled in, the physical examination will be performed and an x-ray of the shoulder will take place.

Study burden and risks

During the appointment an x-ray of the shoulder will be made. The total radiation exposure in this study is 0.001 mSv. This exposure has a minimal risk of health damage

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

- Age: 18-80 years
- Diagnosed with a coracoid fracture of at least 6 months old
- Has been treated in the Spaarne Gasthuis or Bergman Clinics
- A signed informed consent
- Ability to read or write the Dutch language

Exclusion criteria

- Age: <18 years or >80 years
- Diagnosed with a coracoid fracture of less than 6 months old.
- Inability to read or write the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2017
Enrollment:	12
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-08-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	28-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL60709.094.17