Evaluation of the DogBone Button technique as a surgical intervention for AC ligament reconstruction on functionality and/or patient satisfaction; a case series.

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What is the functional status of patients who have been treated using the dogbone Button technique as surgical treatment or by means of conservative treatment of acute acromioclavicular luxation at least 3 months and up to 24 months after surgery?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42691

Source ToetsingOnline

Brief title Evaluation of the DogBone Button technique

Condition

• Tendon, ligament and cartilage disorders

Synonym

acromioclavicula luxation; collarbone dislocation

Research involving

Human

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Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: AC luxation, Arthroscopy, Shoulder

Outcome measures

Primary outcome

functional diagnostic testing of the shoulder

Secondary outcome

Secundary outcome are: residual symptoms, complications, satisfaction and

interval to return to work / sport.

Study description

Background summary

Recently, the orthopedic department of the St. Antonius Hospital started to use the DogBone Button, one of the multiple surgical methods to stabilize acute acromioclavicular (AC) luxation. Until now, there is no consensus in the literature about what is the best method to do this. The purpose of the present study is to evaluate the functional status of patients who have undergone an AC stabilization by means of a dogbone Button. Functional status (compared to the contralateral shoulder), radiological findings and any residual complaints are evaluated at least 3 months postoperatively.

Study objective

What is the functional status of patients who have been treated using the dogbone Button technique as surgical treatment or by means of conservative treatment of acute acromioclavicular luxation at least 3 months and up to 24 months after surgery?

Study design

observational study, case series

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Study burden and risks

Patients are asked to visit the clinic once for a comprehensive physical examination of the shoulder and to complete a set of questionnaires. The visit will last approximately 30 minutes. Since there is only one physical examination and no intervention there will be no risks associated with this study.

Contacts

Public Sint Antonius Ziekenhuis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Acute AC luxation >18 years of age

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AC stabilisation using DogeBone button between january 2013 and the present or patients with a Rockwood 3 or higher treated conservative.

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2015
Enrollment:	40
Туре:	Actual

Ethics review

Approved WMO	
Date:	20-10-2015
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 CCMO **ID** NL54527.100.15