

The open modified Bankart procedure: long term follow up study

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How do patients experience the long-term outcome after primary open modified Bankart surgery for patients with instability problems after AFASD?

Ethical review	Approved WMO
Status	Completed
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57708

Source

ToetsingOnline

Brief title

Long term follow up after open Bankart procedure

Condition

- Joint disorders

Synonym

recurrent shoulder dislocation, Shoulder instability

Research involving

Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: de Stichting research orthopedie Delft vergoedt de kosten voor het polibezzoek. Een subsidie zal aangevraagd worden wij de wetenschappelijke activiteiten commissie van het RdGG voor de kosten van de rontgenfoto's.

Intervention

Keyword: Acute shoulder dislocation, Long term follow up, Open modified Bankart procedure

Outcome measures

Primary outcome

The primary endpoint of this study is the amount of instability, 15-25 years after open modified Bankart surgery. Instability will be measured with the Rowe score.

Secondary outcome

Secondary endpoints are the prevalence of arthrosis, pain, physical functioning, quality of life and complications

Study description

Background summary

The best treatment of acute first-time anterior shoulder dislocation AFASD in young patients is a debated issue, most published studies have a short follow-up. Although, in patients with recurrent dislocations or in selected patients who are active in sports surgical treatment is propagated. In Reinier de Graaf Groep Hospital (RdGG), the open modified Bankart procedure was started in 1989 and was always carried out in the same way by two senior orthopaedic surgeons. With the current research, we would like to study the long term results of the open modified Bankart procedure.

Study objective

How do patients experience the long-term outcome after primary open modified Bankart surgery for patients with instability problems after AFASD?

Study design

We will perform a cohort study of patients after open modified Bankart surgery who have been treated for patients with instability problems after AFASD, 10-25 years ago in Reinier de Graaf Hospital (RdGG) Hospital.

Study burden and risks

There are no benefits for patients participating in this study. X-rays will be made of both shoulders, once.

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

- * Patients aged 18 years and older;
- * Patients willing to participate;
- * Patients who had primary open modified Bankart surgery between January 1989 and January 2000
- * Patients able to speak and write the Dutch language.

Exclusion criteria

- Patients who had surgery of the contralateral shoulder

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 09-07-2015

Enrollment: 31

Type: Actual

Ethics review

Approved WMO

Date: 29-04-2015

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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	NL52656.098.15