Long-term results of acromioplasty and bursectomy versus bursectomy alone in the treatment of subacromial impingement syndrome. Clinical and radiological outcome after 8-13 years.

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The aim is to study the long-term functional and radiological results (i.e. cuff integrity) of arcromioplasty in patients with SIS after a 8-13 year follow-up period.

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

Summary

ID

NL-OMON40741

Source
ToetsingOnline

Brief title
LESIS

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Impingement Subacromial-pain-syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Reumafonds;daarnaast loopt er een aanvraag bij het Annafonds

Intervention

Keyword: acromioplasty, bursectomy, impingement, subacromial pain syndrome

Outcome measures

Primary outcome

De primary clinical outcome is the Constant Murley Score and the primary

radiological outcome is the presence of a partial or full-thickness rotator

cuff tear on MR-arthrography.

Secondary outcome

Clinical evaluation (measured by validated questionnaires)

Simple Shoulder Test

Visual Analogue Scale (VAS) for pijn during shoulder movement and in rest

Western Ontario Rotator Cuff Index (Disease specific quality of life)

Anchor questions on treatment outcome evaluation on a Likert Scale

Radiological evaluation:

Occupation ratio en cross-sectional surface area

Fatty degeneration measured by using the Goutallier classificatie

Acromial shape (Bigliani)

Acromiohumoral cranialisation (AH distance)

Type and extend of the rotator cuff tear

Study description

Background summary

The subacromial impingement syndrome has a high incidence in patients aged 40-60 years and has a major impact on daily life and job-specific activities. When complaints of shoulder pain persists after conservative treatment approaches are unsuccesful, the acromioplasty is performed. Nevertheless, the results of the acromioplasty are highly variable and it is unclear if damage to subacromial structures is prevented by an acromioplasty. Clinical results do not depent on the type of surgical procedure (acromioplasty in combination with bursectomy or bursectomy) after a short-term follow-up. However long-term follow-up is needed as rotator cuff degenerate with time and consequences of extrinsic compression migh be only seen with long-term follow-up. We hypothesise that long-term clinical and radiologic results are comparable between acromioplasty in combination with a bursectomy and bursectomy. Therefore the aim is to study the long-term functional and radiological results (i.e. cuff integrity) of arcromioplasty in patients with SIS after a 8-13 year follow-up period.

Study objective

The aim is to study the long-term functional and radiological results (i.e. cuff integrity) of arcromioplasty in patients with SIS after a 8-13 year follow-up period.

Study design

Follow-up study of a randomized controlled study cohort with a 8-13 jaar follow-up period.

Study burden and risks

Patients are requested to complete validated shoulder questionnaires to assess shoulder function and shoulder specific quality of life (15 min). Furthermore patients are invited for an clinical evaluation at the outpatient clinic (15 min). Afterwards patients will be investiged by a MR arthrography in order to study radiologic parameters and especially the presence of a rotator cuff tear(30min). The estimated total time is 60 min.

Intra-artricular contrast used in MR arthrography has limited (<0.1%) complication risks. These risks include septic arthritis, cellulitis and an allergic reaction.

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 were previously included according to the inclusion and exclusion criteria used in the conducted randomized controlled trial by Henkus et al, JBJS [BR], 2009. ;The previous inclusion criteria were:
Nontraumatic pain in the deltoid region
Inability to lie on the affected side.
Pain provocation by abduction and retroversion or internal rotation.
Positive Neer test
Positive Hawkins test
positive lidocaine impingement test;Exclusion criteria:
Limitiations in passive range of motion.
Glenohumeral instability
Any form of arthritis in the glenohumeral or acromioclavicular joint

Biceps tendinitis
Rotator cuff tear
Cervical radiolopathy
Calcifying tendonitis;All previous included patients are included in the current trial.

Exclusion criteria

Only patients who suffered from a fracture/trauma are excluded in the current trial

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2015
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL49198.098.14