SISTIM: Subacromial Impingement Syndrome: The Identification of etiologic Mechanisms
will have a new acronym respectively, SuSy
SuSy: Subacromial Impingement Syndrome: The Identification of etiologic Mechanisms

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Organization of distinct etiological mechanisms for symptoms clinically diagnosed as SIS, into several identifiable subgroups of patients (relative cranialisation of the humerus, structural narrowing of the subacromial space, subacromial...

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

Summary

ID

NL-OMON41430

Source
ToetsingOnline

Brief title
SISTIM, new acronym, SuSy

Condition

- Joint disorders

Synonym
painful arc syndrome, subacromial pain syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: Etiology, Impingement, Pathophysiology, Subacromial

Outcome measures

Primary outcome

Primary study parameters:

- Cranial translation of the humerus as measured on AP-radiographs in rest, and with a constant abduction and adduction force exertion against an force transducer

- Scapulohumeral rhythm and shoulder-arm Range of Motion as measured with an electromagnetic motion tracking device.

Secondary outcome

All study parameters categorized for etiological subgroups:

1) Relative cranial translation of the humerus: 3D arm-scapula motion registration (3D RoM), muscle activation parameters of shoulder and rotator cuff muscles (EMG), static acromiohumeral distance (sAH) on AP-radiographs *at rest* and with exerted ab- and adduction moments (dAH), integrate bony 3D-shape

with 3D RoM to describe dynamic AH (3DdAH).

2) Structural (bony) narrowing of the subacromial space: shape parameters of scapula (i.e. Bigliani acromion classification) and humerus, 3D kinematic analysis of scapulo-humeral motion by integration of bony 3D-shapes with 3D RoM.

3) Subacromial inflammatory processes and damaged tissues: MRI for rotator cuff and muscle quality (Goutallier score) and signs of bursitis, tendinitis and rotator cuff ruptures.

4) Other primary pathologies leading to SIS complaints: evaluation of MRI and radiographs for acromioclavicular-osteoarthritis, full thickness rotator cuff-ruptures, coracoid impingement and other subacromial pathologies.

Study description

Background summary

The subacromial impingement syndrome (SIS) is the most prevalent disorder of the shoulder in primary health care. Acromionplasty, as the main surgical treatment of SIS, is one of the most performed orthopedic surgeries.

The etiology of the primary SIS is not clearly understood, but surgical treatment is primarily focused at the extrinsic mechanism as described by Neer: the anterior part of the acromion painfully impinges on the subacromial tissues and therefore must be resected. Nevertheless, variable results of this frequently performed procedure have been reported (successful in 48- 90%), and there are numerous publications of successful (conservative) treatments without changing the coracoacromial shape.

There is a lot of debate on the etiology of SIS. Several mechanisms have been described: i.e. narrowing of the subacromial space caused by cranial translation of the humerus in multidirectional instability, scapular dyskinesia, or intrinsic mechanisms such as primary degenerative tendinopathy of the rotator cuff.

In theory, impingement (*narrowing of the subacromial space*) can be caused by several mechanisms. Our hypothesis is, that the extrinsic mechanism is only valid for a subgroup of patients; complaints of SIS can be caused by
1) a pathologic pattern of arm-scapula movements caused by a disrupted balance in muscle forces, leading to cranial translation of the humerus with respect to the scapula, or
2) narrowing of the subacromial space because of anatomic variations (i.e. a hooked acromion or humeral shape), or
3) a subacromial inflammatory reaction (i.e. caused by micro-trauma), or
4) secondary to an adjoining pathology (i.e. osteoarthritis in the acromioclavicular(AC)-joint).

Study objective

Organization of distinct etiological mechanisms for symptoms clinically diagnosed as SIS, into several identifiable subgroups of patients (relative cranialisation of the humerus, structural narrowing of the subacromial space, subacromial inflammatory processes, other primary pathologies), in order to improve diagnostic and therapeutic strategies of SIS by designing concept diagnostics and treatment flow charts for each subgroup.

Study design

Observational cohort study

Study burden and risks

Patients will be subjected to usual care treatment and diagnostics for shoulder complaints, including a standard MRI-arthrogram and radiographs.

Patients will receive a subacromial injection with lidocaine for one of the biomechanical test at the LUMC laboratory.

5 Additional radiographs will be performed: anterior-posterior (AP) radiographs with isometric active adduction and active abduction against a force transducer, and in rest on the affected arm and the sound arm.

At intake, investigations in the laboratory will take about 2 hours. Filling out questionnaires (at home or at the hospital) will take 30 minutes.

In the 3 study related follow-up moments, patients will only be subjected to questionnaires (30 minutes in total).

A potential benefit is the availability of thorough investigations for each patient on short notice and long term follow-up. Additionally, the goal of this study is to lead to more effective diagnostic and treatment strategies,

possibly preventing unnecessary surgery in the future.

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

The clinical diagnosis of stage I or II SIS is made when one or more of the following mentioned factors exist, next to a positive Neer impingement test and a positive Hawkins test.;Patients* history:
- Diffuse unilateral shoulder pain for > 3 months;
- Pain during activities with abduction, retroflexion and/or internal rotation (i.e. closing the door, putting on jacket, overhead activities);
- Pain at night or incapable of lying on the shoulder.;Physical examination:
- Diffuse pain at palpation of the greater tuberosity;
- Disturbed scapulohumeral rhythm;

- Painful arc;
- No complaints or sings of pathologies on the contralateral shoulder;
- > 90 Degrees external rotation in 90 degrees of passive abduction (frozen shoulder);
- Positive Yocum test.

Exclusion criteria

Patients are excluded if one of the following characteristics is found:
- <35 Or > 60 years old
- Restrictions in passive movements of glenohumeral joint/frozen shoulder;
- History of fracture or dislocation of the shoulder;
- History of surgery around the shoulder (in anamnesis);
- Tumors;
- No informed consent;
- Clinical and radiographic signs of comorbidities or alternative diagnoses on the affected shoulder (glenohumeral instability, glenohumeral movement restriction, glenohumeral osteoarthritis or arthritis, rheumatic disorder, labrum lesions, a history of trauma on the affected shoulder, biceps muscle tendinitis, complete (full thickness) rotator cuff rupture, cervical radiculopathy, PASTA lesion, or calcifying tendinitis);
- Contralateral shoulder with clinical signs of shoulder complaints.
- Pacemaker or other electronic implants

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2010
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	25-02-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	19-02-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	10-11-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (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	NL28090.058.09