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Accuracy of the shoulder clinical tests, ultrasonography and magnetic resonance in the diagnosis of the supraspinatus tendon lesions in patients undergoing arthroscopy shoulder surgery

Submission date
02/04/2018

Recruitment status
No longer recruiting

Registration date
18/04/2018

Overall study status
Completed

Last Edited
27/04/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The rotator cuff is the group of muscles and tendons around the shoulder joint. They keep the shoulder stable. These can be injured and tear, or get worn over time (tendinopathy).
It is important to determine the accuracy of clinical tests used to diagnosis rotator cuff injuries, to ensure complete trust in the physical exam. Currently there is an abundant use of image exams of the shoulder, such as ultrasound and MRI, to confirm the clinical diagnosis for patients with shoulder pain complaints.
This study aims to determine the right method and the accuracy of these tests to diagnose tendon problems.

Who can participate?
Adults aged over 18 years with shoulder pain following surgery

What does the study involve?
Participants complete twelve physical tests on their shoulder for examination. Within three months of this, they undergo imaging of their shoulder using ultrasound and MRI. Based on the diagnosis, participants then receive the most suitable surgical procedure or treatment on the joint, when suitable.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for all participants of this study.

Where is the study run from?
1. Hospital São Paulo - Universidade Federal de São Paulo (UNIFESP) (Brazil)

2. Hospital Beneficiente Nipobrasileiro de São Paulo (Brazil)
3. Hospital e Maternidade Christóvão da Gama (Brazil)
4. Universidade de Santo Amaro (Brazil)

When is the study starting and how long is it expected to run for?
October 2016 to April 2019

Who is funding the study?
Universidade Federal de São Paulo – UNIFESP (Brazil)

Who is the main contact?
Mr Fabio Nicolao (Public)

Contact information

Type(s)
Public

Contact name
Mr Fabio Anauate Nicolao

Contact details
Universidade de Santo Amaro
Rua Prof. Enéas de Siqueira Neto
340. Jardim das Imbuias
Sao Paulo
Brazil
04061001

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20180402

Study information

Scientific Title
Diagnostic accuracy study of the shoulder clinical tests and ultrasonography, magnetic resonance in the supraspinatus tendon lesions in patients undergoing arthroscopy shoulder surgery

Study objectives
The empty can test and the ultrasonography may present high accuracy in the diagnosis of the supraspinatus tendon lesions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee on Ethics and Research of UNIFESP (Comitê de Ética e Pesquisa da UNIFESP), 27/04/2017, ref: 1662/2016

Study design
Observational prospective multicentric accuracy study

Primary study design
Observational

Secondary study design
Accuracy study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet: fabionicolao@terra.com.br

Health condition(s) or problem(s) studied
Rotator cuff lesions

Interventions
In this prospective accuracy study, participants undergo a number of tests, listed below:
1. Jobe's test / empty can test: test performed with the arm into medial rotation, elevation of 90°, where the patient is asked to isometrically resist a downward pressure applied by the tester. The test is positive if pain or weakness when performing the maneuver.
2. Full can test: Test performed with a neutral rotation of the shoulder (thumb pointing up), elevation of 90°, and patient is then asked to isometrically resist a downward pressure applied on the arm by the tester. The test is positive if pain or weakness when performing the maneuver.
3. Champagne toast test: Test perfomed with the shoulder in 30° of abduction and mild shoulder external rotation. The test is positive if pain when performing the maneuver.
4. Drop arm test: The test is applied in the plane of abduction, with the patient's arm placed passively above 90° by the tester; the support is removed, and the patient attempts to lower the arm actively. The test is positive if the patient is unable to actively lower the arm under control beyond the horizontal, and it drops to his or her side.
5. Patte's test: With the arm supported in 90° of scaption, the patient is asked to laterally rotate maximally against the tester’s isometric resistance. The test is positive if pain or weakness when performing the maneuver.
6. Resisted lateral test: The patient stands, elbow at side and flexed to 90°, shoulder in neutral rotation. He or she is then asked to laterally rotate the shoulder maximally against the tester’s isometric resistance, which is applied at the wrist. The test is positive if pain or weakness when performing the maneuver.

7. Hawkins' test: The upright patient’s arm is passively positioned in 90° of flexion at shoulder and elbow. The tester then forcibly medially rotates the patient’s shoulder. The test is positive if pain when performing the maneuver.
8. Yocum's test: The patient places the hand of the affected arm on his or her other shoulder and, keeping the point of the affected shoulder down, raises the elbow of the same limb. The test is positive if pain occurs during the maneuver.
9. Neer's sign: The tester forcibly elevates the patient’s arm through scaption, preventing scapular movement by pressing down on the clavicle and acromion with the other hand. Pain constitutes a positive Neer’s sign.
10. Painful arc test: The patient actively elevates, then lowers, the shoulder in the plane of the scapula to full elevation. The test is considered positive if pain during elevation, during lowering, or both.
11. Cross body adduction test: The arm is placed at 90o of flexion and then a passive horizontal adduction is performed by the examiner across the chest. The test is positive if pain occurs when performing the maneuver.
12. Speed's test: The shoulder is placed in 90o of flexion, with the elbow in extension and the supinated forearm. The patient flexes his or her shoulder against isotonic resistance applied to the patient's wrist. The test is positive if localized to the bicipital groove.

Participants then undergo imaging of their shoulder using ultrasounds and magnetic resonance. Ultrasonography: Ultrasound evaluation is performed in the coronal, axial and sagittal planes, with a 10 MHz linear transducer, characterized by the presence of tendinopathy, and partial or total rupture of the supraspinatus tendon.

The clinical tests are all done by a orthopedic specialist in shoulder and elbow surgery and the ultrasounds by a radiologist. The tests are performed individually at the hospital. Clinical tests must be performed within the 3 months before diagnostic imaging exams, either Ultrasonography or MRI. Then the participants are followed up according to their pathology to be undergone the most adequate treatment. Participants with indication of arthroscopic surgical treatment are included in this protocol.

The two different types of diagnosing rotator cuff lesions are compared. Correlation of the location and size of the supraspinatus lesion with the clinical tests measured using arthroscopy findings.

Intervention Type
Mixed

Primary outcome measure
Supraspinatus tendon tears are measured using arthroscopy findings and comparing to the magnetic resonance image and ultrasonography. Tears are classified as tendinopathy, partial tears or full thickness tears.

Secondary outcome measures
1. Level of pain is measured using the visual analogue scale after performing the empty can test (Jobe test)
2. Correlation of the location and size of the supraspinatus lesion with the clinical tests is measured using arthroscopy findings

Overall study start date
10/10/2016

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Patients of both genders
2. Over 18 years old
2. Complaint of shoulder pain with at least 1 month of duration undergoing arthroscopy surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Cognitive alterations of the patient that prevents comprehension of the proposed treatment
2. Lack of outpatient return; image examination with more than three months of clinical evaluation of the patient
3. Traumatic or unexpected event in the affected shoulder between arthroscopy surgery, magnetic resonance image, ultrasonography and physical examination

Date of first enrolment
01/05/2018

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital São Paulo - Universidade Federal de São Paulo (UNIFESP)
Sao Paulo
Brazil
04037020

Study participating centre
Hospital Beneficiente Nipobrasileiro de São Paulo
Sao Paulo
Brazil
02189010

Study participating centre
Hospital e Maternidade Christóvão da Gama
Santo Andre
Brazil
09030340

Study participating centre
Universidade de Santo Amaro
Brazil
04829-300

Sponsor information

Organisation
Universidade de Santo Amaro

Sponsor details
Rua Prof. Enéas de Siqueira Neto
340. Jardim das Imbuias
Sao Paulo
Brazil
04829-300

Sponsor type
University/education

ROR
https://ror.org/05nvmzs58

Funder(s)

Funder type
University/education

Funder Name
Universidade Federal de São Paulo - UNIFESP

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact orthopaedic journal.

Intention to publish date
30/05/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically accessible portal according to the last ICMJE data sharing statement.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		27/04/2020	27/04/2020	No	No