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Accuracy of the shoulder clinical tests and ultrasonography in the diagnosis of the supraspinatus tendon lesions

Submission date
25/09/2017

Recruitment status
No longer recruiting

Registration date
24/10/2017

Overall study status
Completed

Last Edited
07/04/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
The rotator cuffs are the muscles that attach the shoulder blade to the arm and this helps us lift and rotate our arms. Clinical tests are important for to diagnose rotator cuff lesions (tears); however, there is currently an abusive increase in requests for shoulder imaging, especially ultrasound and magnetic resonance imaging, for patients complaining of shoulder pain. The aim of this study is to evaluate the accuracy of these clinical tests and ultrasound of the shoulder in the diagnosis of supraspinatus tendon lesions.

Who can participate?
Adults aged 18 and older who have complained of shoulder pain for at least one month.

What does the study involve?
Participants undergo clinical tests that test their ability to use their shoulder to do a number of different tasks. Participants also undergo imagining (ultrasounds and MRIs) to diagnose their shoulder issues. The two different types of diagnosis are compared for accuracy.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

Where is the study run from?
1. Hospital São Paulo - Universidade Federal de São Paulo (UNIFESP) (Brazil)
2. Hospital e Maternidade Dr. Christóvão da Gama (Brazil)
3. Hospital Beneficiente Nipobrasileiro de São Paulo (Brazil)
4. Hospital Estadual de Diadema (Brazil)

When is the study starting and how long is it expected to run for?
May 2017 to April 2019

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

Who is the main contact?
Mr Yazigi Junior

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20170925

Study information

Scientific Title
Diagnostic accuracy study of the shoulder clinical tests and ultrasonography in the supraspinatus tendon lesions

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)
Comitê de Ética e Pesquisa da UNIFESP, 04/03/2017, ref: 1661/2016

Study design

A prospective multicentric accuracy study of the shoulder tests and ultrasonography in patients of both genders, over 18 years, with complaint of shoulder pain for at least 1 month, compared to magnetic resonance imaging (reference standard). The sensitivity, specificity, positive predictive value, negative predictive value, accuracy and likelihood ratio of these tests will be calculated.

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: junioryazigi73@yahoo.com.br

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

Interventions
In this prospective accuracy study, participants undergo a number of tests including: the Jobe's test / empty can test, full can test, the champagne toast test, drop arm test, Patte's test, resisted lateral test, Hawkins' test, Yocum's test, Neer's sign, painful arc test, cross body adduction test and Speed's test. Participants also undergo imaging of their shoulder using ultrasounds and magnetic resonance.

The tests are as follows:
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 localised to the bicipital groove.

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. The two different types of diagnosing rotator cuff lesions are compared.

Intervention Type
Mixed

Primary outcome measure
Supraspinatus tendon tears are measured using the resonance magnetic image, classified as tendinopathy, partial tears or full thickness tears

Secondary outcome measures
1. Level of the pain that 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 measured using magnetic resonance image

Overall study start date
01/05/2017

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.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
306

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 the MRI, the USG and the physical examination

Date of first enrolment
01/02/2018

Date of final enrolment
30/01/2019

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital São Paulo - Universidade Federal de São Paulo (UNIFESP)
Sao Paulo
Brazil
04024-002

Study participating centre
Hospital e Maternidade Dr. Christóvão da Gama
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Study participating centre
Hospital Beneficiente Nipobrasileiro de São Paulo
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02189-010

Study participating centre
Hospital Estadual de Diadema
Diadema
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09960-120

Sponsor information

Organisation
Universidade Federal de São Paulo - UNIFESP

Sponsor details
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São Paulo
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Sponsor type
University/education

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
University/education

Funder Name
Universidade Federal de São Paulo - UNIFESP

Results and Publications

Publication and dissemination plan
We intend to publish in a high-impact peer reviewed journal. Intention to publish our protocol with the statistical analysis plan.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from João Alberto Yazigi Junior, e-mail: junioryazigi73@yahoo.com.br

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		03/04/2020	07/04/2020	No	No