Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the Effects of High Intensity Laser, Hydrocortisone Phonophoresis and Ultrasound on Pain, Range of Motion, Grip Strength, Upper Limb Function and Quality of Life in Unilateral Subacromial Impingement Syndrome Patients

Protocol summary

Study aim

Determining the effect of high intensity laser, hydrocortisone phonophoresis and ultrasound in comparison on the studied variables (pain score, active and passive range of motion, upper limb function, grip strength and quality of life) in unilateral subacromial impingement syndrome patients

Design

A double blind randomized clinical trial study with three groups on 60 patients with blinded assessor and statistician. The simple randomization method will be used with randomization list generated by Excel Office 2010.

Settings and conduct

60 eligible patients will be allocated randomly into HIL, hydrocortisone phonophoresis, and ultrasound groups. Treatment will be performed in 10 sessions in Biomechanics laboratory of Babol university of medical sciences. Assessment of clinical outcomes will be performed at pre-intervention, the end of the 10 treatment sessions and 1 month follow-up.

Participants/Inclusion and exclusion criteria

Aged 18-55 years, Positive Neer, Hawkins, Empty can and Speed tests in involved side, Positive , Painful range of motion active and passive abduction, flexion, internal rotation and external rotation of involved shoulder, At least 4 weeks have passed since the onset of pain and symptoms on the involved side, Resting pain score above 3 in the subacromial region of the involved side, Confirmation of diagnosis of phase 1 and 2 subacromial impingement syndrome based on Neer criteria in MRI findings

Intervention groups

Eligible patients will be randomly divided into 3 groups. In group 1 patients will receive HILT and TENS. In group 2 hydrocortisone phonophoresis and TENS and in group 3 ultrasound and TENS will be applied. Assessment of the outcomes including pain, shoulder range of motion, grip strength, upper limb function and quality of life will be done at pre-intervention, the end of the 10 treatment sessions and 1month follow-up.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040539N3**
Registration date: **2021-08-30, 1400/06/08**
Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**
Update count: **0**

Registration date

2021-08-30, 1400/06/08

Registrant information

Name

Roghayeh Mousavi-khatir

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-09-01, 1400/06/10
Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effects of High Intensity Laser, Hydrocortisone Phonophoresis and Ultrasound on Pain, Range of Motion, Grip Strength, Upper Limb Function and Quality of Life in Unilateral Subacromial Impingement Syndrome Patients

Public title
Comparing the Effects of High Intensity Laser, Hydrocortisone Phonophoresis and Ultrasound in Unilateral Subacromial Impingement Syndrome Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18-55 years Positive Neer and Hawkins tests in involved side Positive Empty can and Speed tests in involved side Painful range of motion active and passive abduction, flexion, internal rotation and external rotation of involved shoulder At least 4 weeks have passed since the onset of pain and symptoms on the involved side Resting pain score above 3 in the subacromial region of the involved side Confirmation of diagnosis of phase 1 and 2 subacromial impingement syndrome based on Neer criteria in MRI findings
Exclusion criteria:
Radicular pain in involved upper limb Glenohumeral and acromioclavicular joint osteoarthritis History of shoulder surgeries history of acute trauma to the shoulder girdle History of humerus head fractures on the involved shoulder Frozen shoulder Thyroid diseases Heart disease and pacemaker Pregnancy Skin complications in the treated area Tumor Active cancer or a history of cancer less than one year after treatment Epilepsy Photosensitive diseases Mental illness Systemic and metabolic diseases Diabetes Presence of calcium deposition, complete or incomplete rupture in rotator cuff tendons and long head of biceps Fibromyalgia Physiotherapy or drug injections to reduce pain in the subacromial area at the same time as the study
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
2
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The simple randomization method will be used; Randomization list will be generated based on a computer program (Excel Office 2010) by a researcher who has no role in recruitment and evaluation process. Based on the results of randomization, the same researcher will be responsible for treating all patients belonging to each of the three groups of high intensity laser, hydrocortisone phonophoresis and ultrasound in all sessions.
Blinding (investigator's opinion)
Double blinded
Blinding description
At first the patients will be visited by an Orthopedic specialist who will determine eligible participants based on inclusion and exclusion criteria and will referred them to a physiotherapy specialist who will evaluate the clinical outcomes. Then all eligible patients will be randomized and allocated into three treatment groups (HIL, Hydrocortisone phonophoresis and US) by a researcher who is not involved in recruitment and evaluation process. This same researcher will be responsible for treating all patients belonging to each of the three groups in all sessions. This researcher will not disclose the programmed intervention to the other researchers involved in the study until its final completion. Assessment of the outcomes at the end of the 10 treatment sessions and 1month follow-up will be performed by the same assessor who carried out the first evaluation. Eventually, collected data will be analyzed by a blind statistician. Thus assessor and statistician will be blinded throughout the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Science, Ganjafrouz Ave
City
Babol
Province
Mazandaran
Postal code
47176-47745
Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.MUBABOL.REC.1400.088

Health conditions studied

1

Description of health condition studied

Unilateral Subacromial Impingement Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain at rest

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Visual Analog Scale

2

Description

Pain while moving

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Shoulder active flexion range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

2

Description

Shoulder active abduction range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

3

Description

Shoulder active external rotation range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

4

Description

Shoulder active internal rotation range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

5

Description

Shoulder passive flexion range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

6

Description

Shoulder passive abduction range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

7

Description

Shoulder passive external rotation range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

8

Description

Shoulder passive internal rotation range of motion

Timepoint

Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session

Method of measurement

Standard plastic goniometer

9

Description
Hand grip
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Dynamometer SEAHAN 5001

10

Description
Upper limb function
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Quick DASH questionnaire

11

Description
Quality of Life
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
SF-36 questionnaire

Intervention groups

1

Description
Intervention group: HIL group: HIL will be applied using the Delta Laser New Age device (Italy) with a wavelength of 980 nm and 13 W maximum power output with probe diameter of 1 cm. The treatment will be consisted of three phases in each session. The initial phase will involve a peak power of 13 W, average power of 3/90 W, duty cycle 30% and 111 J energy. The intermediate phase will be applied a peak power of 13 W, average power of 6/5 W, duty cycle 50% and 1852 J energy. The final phase will be performed with a peak power of 13 W, average power of 3/90 W, duty cycle 30% and 111 J energy the same as the initial phase. HIL treatment will be included 15 min application time (each phase 5 min), and total energy of 4074 J in each session. Probe will be held in contact with the dry skin previously cleaned with alcohol, at 90 degree angle perpendicular to the On the anterior and superior surface of the shoulder joint in affected side. The hand piece will be moved slowly to the intended area.
Category
Rehabilitation

2

Description
Control group: Phonophoresis hydrocortisone group: An ultrasound device (215P Novin, Iran) will be used with a frequency of 1 MHz, an intensity of 1/2 watts per centimeter and a 60% duty cycle for 5 minutes on the anterior and superior surface of the shoulder joint. Hydrocortisone 1% gel will be used for phonophoresis. The probe is moved vertically, in full contact with the skin surface, in gentle circular motions lasting 3 seconds along each circular motion.
Category
Rehabilitation

3

Description
Control group: Ultrasound group: All conditions and settings of the device will be exactly the same as those mentioned in the use of phonophoresis, the difference is that instead of hydrocortisone 1% gel, non-therapeutic conductive gel is used to increase the absorption of waves.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid Government Super Specialty Clinic
Full name of responsible person
Seyyede Roghayeh Mousavi Khatir
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Sponsors / Funding sources

1

Sponsor
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
I have not decided yet

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available