

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

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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

AgeFrom **18 years** old to **55 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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

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Babol University of Medical Science, Ganjafrouz Ave

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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

Name of organization / entity

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Full name of responsible person

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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**

Babol University of Medical Sciences

Full name of responsible person

Pardis Norouzi

Position

Master's Degree student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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