

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of Dexamethasone phonophoresis versus placebo efficacy on burn hypertrophic scar characteristics

Protocol summary

Summary

Objectives: We want to introduce an alternative and less invasive method in management of hypertrophic burn scar. **Design:** Double-blinded randomized clinical trial **Method:** In this double-blinded randomized clinical trial, 56 patients with hypertrophic burn scar due to burn injury based on following criteria will allocate randomly to Dexamethasone and control group(each group 28 individual). Patients in both group will have routine burn scar therapy but individuals in intervention group will receive 10 sessions of Dexamethasone 0.4% phonophoresis (3 sessions/ wk) and individuals in control group will have placebo phonophoresis (ultrasound with normal routine aquatic gel without any Dexamethasone) with the same protocol. Phonophoresis sessions will be accomplished by our physiotherapist . Base line and follow-up visits will be done by one of our authors. Both the physiotherapist and our physiatrist who visits patients are blinded to group randomization. Hypertrophic scar characteristics and pruritus will be measured by "Vancouver Scar Scale(VSS)", and "5-D Pruritus Scale" respectively in both groups. In the last session of treatment program and one week after, same measurements will be done. Pain perceived during phonophoresis subjectively will be recorded by "Visual Analog Scale" in both group in every session of phonophoresis therapy. **Participants:** Inclusion criteria: age between 18-65 years old; at least 8 weeks post injury; scar size below 25 cm square Exclusion criteria: Diabetes mellitus; clinical anemia ; peripheral vascular disease; hypotension; congestive heart failure; immunodeficiency; chemotherapy; malignancy; lactation; pregnancy; near brain, eye and reproductive organ **Intervention:** We use pulsed ultrasound with 1-1.5 watt per centimeter square intensity and 1 mega hertz frequency for maximum 7 minutes in each session. We use Dexamethasone 0.4% gel and common aquatic ultrasound gel in intervention and control group respectively. **Primary outcome:** Hypertrophic scar

characteristics

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407184104N4**

Registration date: **2015-04-06, 1394/01/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-06, 1394/01/17

Registrant information

Name

Mohammad Rahbar

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1544 6694

Email address

rahbarm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Tabriz medical science university

Expected recruitment start date

2015-03-10, 1393/12/19

Expected recruitment end date

2015-09-11, 1394/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Dexamethasone phonophoresis versus placebo efficacy on burn hypertrophic scar characteristics

Public title
Hypertrophic burn scar

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age between 18-65 years old; at least 8 weeks post injury; scar size below 25 cm square
Exclusion criteria: Diabetes mellitus; clinical anemia ; peripheral vascular disease; hypotension; congestive heart failure; immunodeficiency; chemotherapy; malignancy; lactation; pregnancy; near brain, eye and reproductive organ

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz Medical Science University Ethics Committie

Street address
3rd floor, Central building number 2, Tabriz medical science university, Golgasht St

City
Tabriz

Postal code

Approval date
2015-02-23, 1393/12/04

Ethics committee reference number
93178

Health conditions studied

1

Description of health condition studied
Hypertrophic burn scar

ICD-10 code
L91.0

ICD-10 code description
Hypertrophic scar

Primary outcomes

1

Description
Hypertrophic Scar Characteristics

Timepoint
begining, last session and one week after intervention

Method of measurement
Vancouver Scar Scale

Secondary outcomes

1

Description
Scar pruritus

Timepoint
begining, last session and one week after intervention

Method of measurement
5-D Pruritus Scale

Intervention groups

1

Description
Intervention group: Dexamethasone 0.4 % gel phonophoresis for maximum 7 minutes in each session for total 10 session by pulsed ultrasound with 1-1.5 watt per centimeter square intensity and 1Mega Hertz frequency

Category
Rehabilitation

2

Description
Control group: Common aquatic gel phonophoresis for maximum 7 minutes in each session for total 10 session by pulsed ultrasound with 1-1.5 watt per centimeter square intensity and 1 mega hertz frequency

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical medicine and rehabilitation research center

Full name of responsible person

Dr. Mohammad Rahbar

Street address

Physical medicine and rehabilitation ward, Imam Reza hospital, Golgasht St.

City

Tabriz

Physical medicine and rehabilitation ward, Imamreza hospital, Golgasht St.

City

Tabriz

Postal code**Phone**

+98 41 3336 1928

Fax**Email**

ar_pishgahi@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Tabriz Medical Science University

Full name of responsible person

Dr. Mohammadreza Rashidi

Street address

3rd floor, Central building number 2, Tabriz Medical Science University, Golgasht St.

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor of research, Tabriz Medical Science University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Physical medicine and rehabilitation group, Tabriz medical science university

Full name of responsible person

Alireza Pishgahi

Position

Resident

Other areas of specialty/work**Street address**

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz medical science university

Full name of responsible person

Mohammad Rahbar

Position

Physical medicine and rehabilitation Assistant Professor

Other areas of specialty/work**Street address**

Physical medicine and rehabilitation ward, Imamreza hospital, Golgasht St.

City

Tabriz

Postal code**Phone**

+98 41 3336 1928

Fax**Email**

rahbarm@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Physical medicine and rehabilitation group

Full name of responsible person

Alireza Pishgahi

Position

Resident

Other areas of specialty/work**Street address**

Physical medicine an rehabilitation ward, Imamreza hospital, Golgasht St.

City

Tabriz

Postal code**Phone**

+98 41 3337 3967

Fax**Email**

ar_pishgahi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty