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 groups 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

Registrant information
Name
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Name of organization / entity
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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**
- Double blinded

**Blinding (investigator's opinion)**
- Placebo

**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

### 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
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
Vice chancellor of research, Tabriz Medical Science University
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
empty
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
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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 |