

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The evaluation of efficacy of TCA (TriChloroAcetic Acid) 33% in compression with placebo (vaseline) in the treatment of lip fissuring due to retinoids

#### Protocol summary

##### Summary

In the present study, we assay the effect of TCA (trichloroacetic acid) 33% on treatment of lip fissuring and cheilitis due to retinoids; the study has been designed single-blind randomized clinical trial. Inclusion criteria includes men and women aged 18 to 70 years; contact with other topical medications would be stopped two weeks before treatment; patients who sign informed consent; willing to participate in the study considering the visit requirements. Patients are divided in two groups of 37 people (Treatment) TCA (used four times within a month) and the other group (control) use Vaseline for a month. The patients who have a history of contact dermatitis to drugs; patients with acute localized infection; pregnant and lactating mothers; have OCD with digging lips habits; No satisfaction to participate at any stage of the study are excluded .The outcomes of survey are recovery rate after one month treatment according to physicians global score (0-5), satisfaction of patients according to patient global score (0-10).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201301169800N4**

Registration date: **2013-03-27, 1392/01/07**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-03-27, 1392/01/07

##### Registrant information

##### Name

Parvin Mansouri

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6659 5911

##### Email address

mansorip@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Skin stem cell research center, Tehran University of Medical sciences

##### Expected recruitment start date

2013-04-04, 1392/01/15

##### Expected recruitment end date

2013-11-06, 1392/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of efficacy of TCA (TriChloroAcetic Acid) 33% in compression with placebo (vaseline) in the treatment of lip fissuring due to retinoids

##### Public title

The evaluation of efficacy of TCA (TriChloroAcetic Acid) 33% in the treatment of lip fissure due to retinoids

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria : Patient age ranged from 18 to 70 years; contact with other topical medications would be stopped two weeks before treatment; patients who are

able to read, understand and sign patient informed consent; Willing to participate in the study considering the visit requirements . Exclusion criteria: The patient had a history of contact dermatitis to the drugs; patients with acute localized infection; pregnant and lactating mothers; have OCD with digging lips habits; No satisfaction to participate at any stage of the study.

#### **Age**

From **18 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **37**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of Medical Sciences and Health Services

##### **Street address**

Central administration of university, Ghodss St., Keshavarz Blvd

##### **City**

Tehran

##### **Postal code**

1417653761

##### **Approval date**

2012-11-17, 1391/08/27

##### **Ethics committee reference number**

91-03-150-19582-70437

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

Lip fissuring

#### **ICD-10 code**

K13.0

#### **ICD-10 code description**

Diseases of lips

### **Primary outcomes**

#### **1**

#### **Description**

Healing rate based on physicians global score (0-5) after one month treatment

#### **Timepoint**

Four session with weekly period

#### **Method of measurement**

Inspection & compare the photos by dermatologist before & after treatment

### **Secondary outcomes**

#### **1**

#### **Description**

Patient satisfaction

#### **Timepoint**

Four session with weekly period

#### **Method of measurement**

Patient global score (0-10)

### **Intervention groups**

#### **1**

#### **Description**

TCA usage, 4 times with weekly interval

#### **Category**

Treatment - Drugs

#### **2**

#### **Description**

Vaselin cream applying 1 month

#### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Skin clinic of Imam Khomeini hospital

##### **Full name of responsible person**

Dr. Parvin Mansouri

##### **Street address**

Imam Khomeini hospital, Keshavarz Blvd.

##### **City**

Tehran

### **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Parvin Mansouri

**Street address**

Skin Ward, Imam Khomeini Hospital

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**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**

Shahid Beheshti University of Medical sciences

**Full name of responsible person**

Dr. Somaih Hejazi

**Position**

Dermatology Resident

**Other areas of specialty/work**

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Shohada e Tajrish hospital, Tajrish sq.

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+98 21 2274 1507

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dr.s.hejazi@gmail.com

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### Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Parvin Mansouri

**Position**

Dermatologist

**Other areas of specialty/work**

**Street address**

Skin Ward, Imam Khomeini Hospital, Khashavarz Blvd.

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mansorip@sina.tums.ac.ir

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### Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Parvin Mansouri

**Position**

Dermatology, professor

**Other areas of specialty/work**

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**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*