

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)

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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 Unuversity of Medical sciences

Full name of responsible person

Dr. Somaih Hejazi

Position

Dermatology Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

Full name of responsible person

Dr. Parvin Mansouri

Position

Dermatologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran Univeristy 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