

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Double blind Randomized Clinical trial of Comparison between Vaseline and Sterile Ophthalmic Vitamin A ointment effect, in treatment of Exfoliative Cheilitis in Girls Dormitory of Shahid Sadoughi University of Medical Sciences

Protocol summary

Summary

Exfoliative cheilitis is an inflammatory condition which is accompanied by regular peeling of superficial keratin layer on lips. The unpleasant appearance and dryness of lips in this condition could be the cause of complaint and discontent in patients. The aim of this study was to compare the therapeutic effect of Vaseline with Sterile ophthalmic Vitamin A ointment in Exfoliative cheilitis treatment. In this clinical trial study, 30 female patients who had this lesion, from the Dormitory of Medical Sciences University, were selected and divided randomly and double-blinded into two groups of Vitamin A and Vaseline. The patients applied the drug topically, 3 times daily for 1 week as directed. Improvement of both groups, which include the severity and size of lesions were measured before drug usage and on the 2nd, 4th and 7th day after drug usage and the results were reported. Inclusion criteria include lack of systemic disease and non-consumption of drugs which make the skin dry. Exclusion criteria include non-cooperation while doing the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052717879N1**
Registration date: **2014-07-07, 1393/04/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-07, 1393/04/16

Registrant information

Name

Zeynab Karimi

Name of organization / entity

Yazd, Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2013-06-30, 1392/04/09

Expected recruitment end date

2014-06-30, 1393/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind Randomized Clinical trial of Comparison between Vaseline and Sterile Ophthalmic Vitamin A ointment effect, in treatment of Exfoliative Cheilitis in Girls Dormitory of Shahid Sadoughi University of Medical Sciences

Public title

Comparison of the therapeutic effect of Vaseline and Sterile ophthalmic Vitamin A ointment in treatment of Lip dryness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: lack of systemic disease, non consumption of drugs which make the skin dry. Exclusion criteria: non-cooperation while doing the study

Age

From **18 years** old to **24 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Double blind means neither the researcher nor the patients know about the type of used drug in the accomplished study. Randomization: using the random-number table, 30 participated patients in the study, were divided into two groups of 15.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Central Department of Medical Sciences, Homafar St., Bahonar Sq.

City

Yazd

Postal code

Approval date

2013-07-13, 1392/04/22

Ethics committee reference number

17/1/71399/پ

Health conditions studied

1

Description of health condition studied

Exfoliative cheilitis

ICD-10 code

K13.0

ICD-10 code description

Diseases of lips

Primary outcomes

1

Description

Severity of lesion on the lip

Timepoint

Before drug usage, on the 2nd day, 4th day and 7th day after drug usage

Method of measurement

Quaternion ranking

2

Description

Size of lesion on the lip

Timepoint

Before drug usage, on the 2nd day, 4th day and 7th day after drug usage

Method of measurement

Transparent graph paper

Secondary outcomes

empty

Intervention groups

1

Description

Second intervention group: 34 gram tube containing medical Vaseline from Firooz Mfg.Co.Tehran- Iran for one week, three times daily.

Category

Treatment - Drugs

2

Description

First intervention group: Sterile ophthalmic Vitamin A with Xerovit trademark name and containing 250 IU/g Vit.A Palmitate in 5 gram aluminum tubes, made in Sina Darou Co. for one week, three times daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Girl's dormitory of Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zeynab Karimi

Street address

Daneshjoo Blvd., Imam Hosein Sq.

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Yazd Shahid Sadoughi
University of Medical Sciences

Full name of responsible person

Fateme Ezzodini

Street address

Central Department of Medical Sciences, Homafar St.,
Bahonar Sq.

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Yazd Shahid Sadoughi
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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zeynab Karimi

Position

Dental Student

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