

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of effect of Simvastatin ointment and Triamcinolone ointment on improvement of psoriatic plaques in 15 patients with chronic plaque psoriasis in a 4 week period.

Protocol summary

Summary

Aim: Introduction of a drug for treatment of Chronic Plaque Psoriasis, in order to reduce the complications and also to increase efficacy of treatment. Study design: 15 patients who fulfill the inclusion criteria will be included in the study. Each patient will be given two boxes, one containing Simvastatin ointment 3% and the other containing Triamcinolone ointment 0.05%. Neither the examiner nor the patients know the content of boxes. Each ointment will be applied on a specific lesion twice a day with the same amount. The lesions will be scored according to PASI score three times during the study period, on 0, 7 and 28th day. Evaluation will be done by a dermatologist and pictures will be taken from the lesion in each visit. Objectives: Evaluation of effect of Simvastatin on treatment of chronic inflammation. Possibility of replacing Simvastatin with current corticosteroid treatments. Inclusion criteria: Age between 18 and 50years; with diagnosis of chronic plaque psoriasis on extensors surfaces of elbow or knee; Each patient must have at least two symmetric lesions; patient must fill out the inform consent form; Patient must have a negative history of treatment for at least 6 months; Patient must not have chronic debilitating disease. Exclusion criteria: Allergic reaction to the medication; if he/she is unwilling to continue; plaque is infected before or during treatment. Intervention: One of the two lesions is randomly chosen to be treated with 3% Simvastatin ointment and the symmetric lesion will be treated with 0.05% Triamcinolone ointment. Each lesion's change will be compared with itself. Variables: Erythema, scaling, surface area.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122015334N2**

Registration date: **2014-02-20, 1392/12/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-20, 1392/12/01

Registrant information

Name

Sina Jelodar

Name of organization / entity

Shiraz university of medical science, student research committee

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences.

Expected recruitment start date

2013-12-15, 1392/09/24

Expected recruitment end date

2015-08-15, 1394/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of Simvastatin ointment and Triamsinolone ointment on improvement of psoriatic plaques in 15 patients with chronic plaque psoriasis in a 4 week period.

Public title

Simvastatin, a drug with immune-modulatory effect.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients arriving at dermatology clinic at Faghihi hospital, with age between 18 and 50years; with diagnosis of chronic plaque psoriasis on extensors surfaces of elbow or knee; Each patient must have at least two symmetric lesions; patient must fill out the inform consent form; Patient must have a negative history of treatment for at least 6 months; Patient must not have chronic debilitating disease. Exclusion criteria: If patient develops reaction to the drug; if he/she is unwilling to continue the treatment; If the plaque is infected during or before treatment.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **15**

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**

Shiraz university of medical science, ethic committee.

Street address

Ethic committee, Shiraz university of medical science, Zand street, Shiraz, Fars.

City

Shiraz

Postal code**Approval date**

2013-12-15, 1392/09/24

Ethics committee reference number

ct-p-92-5218

Health conditions studied**1****Description of health condition studied**

Plaque psoriasis

ICD-10 code

L40.0

ICD-10 code description

A common genetically determined, chronic, inflammatory skin disease characterized by rounded erythematous, dry, scaling patches. Psoriatic lesions have a predilection for nails, scalp, genitalia, extensor surfaces, and the lumbosacral region; the patholog

Primary outcomes**1****Description**

scaling

Timepoint

0, 2nd, 4th week.

Method of measurement

The photos will be compared by two dermatologist who are unaware of type of medication for each lesion.

2**Description**

Erythema

Timepoint

0, 2nd, 4th week.

Method of measurement

The photos will be compared by two dermatologist who are unaware of type of medication for each lesion.

3**Description**

Area

Timepoint

0, 2nd, 4th week.

Method of measurement

The surface area of th lesions will be calculated by two dermatologists by using photos of the lesions. None of the dermatologists know the treatment used for each lesion.

Secondary outcomes**1****Description**

Changes in PASI score.

Timepoint

0, 2nd, 4th week.

Method of measurement

According to PASI score by a dermatologist.

Intervention groups

1

Description

Control group: 0.05% Triamcinolone ointment will be applied twice a day on one of the lesions till the end of study.

Category

Treatment - Drugs

2

Description

Treatment group: 3% Simvastatin ointment will be applied on the symmetric lesion, twice a day till the end of study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic at Faghihi hospital.

Full name of responsible person

Dr. Shahin Aghai.

Street address

Dermatology clinic, Faghihi hospital, Zand street, Shiraz, Fars.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences.

Full name of responsible person

Dr. GH Hatam.

Street address

Research committee, Shiraz University of Medical sciences, Zand street, Shiraz, Fars.

City

Shiraz

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, Shiraz 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

Shiraz University of medical sciences.

Full name of responsible person

Sina Jelodar.

Position

Medical student.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor.

Other areas of specialty/work

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Person responsible for updating data

Contact

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