Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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.

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)

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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.
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Medical student.
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Person responsible for scientific inquiries

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Associate professor.
Other areas of specialty/work
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Web page address

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