

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the efficacy of Tacrolimus ointment and Clotrimazole cream in the treatment of tinea versicolor

Protocol summary

Summary

The study is designed to compare the efficacy of topical tacrolimus and topical clotrimazole in the treatment of tinea versicolor. The study is a randomized, triple-blind, controlled with standard treatment, unicenter, phase II clinical trial. Inclusion criteria include clinical diagnosis of tinea versicolor, confirmation of diagnosis by Wood's lamp examination (Yellow fluorescence) and Direct smear, patients of 10 year old and over, and less than 15% of body surface area involvement. Exclusion criteria include pregnancy or lactation, history of hypersensitivity to main or preservative ingredients of topical tacrolimus or clotrimazole, serious skin or systemic diseases, and history of consumption of topical or systemic antifungal medications in the recent 1 month before enrolling in the study. The patients were selected by convenient sampling from tinea versicolor patients referred to dermatology clinic of Faghihi hospital in Shiraz and 50 patients were enrolled in the study. The patients were divided into two groups with 25 patients in each by block randomization. Intervention group applied tacrolimus 0.03% ointment on tinea versicolor skin lesions two times a day for 21 days and control group applied clotrimazole 1% cream on tinea versicolor skin lesions two times a day for 21 days. Primary outcome measures were Wood's lamp fluorescence, scale and hyperpigmentation grade, and Malassezia species positivity which were assessed in the 0, 3rd, and 5th week of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021216557N1**

Registration date: **2016-06-30, 1395/04/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-30, 1395/04/10

Registrant information

Name

Mozhdeh Sepaskhah

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 712125239

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sepaskhah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research council of Shiraz University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-06-07, 1394/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Tacrolimus ointment and Clotrimazole cream in the treatment of tinea versicolor

Public title

Efficacy of Tacrolimus ointment in the treatment of tinea versicolor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clinical diagnosis of tinea versicolor; Confirmation of diagnosis by Wood's lamp examination (Yellow fluorescence) and Direct smear; Patients of 10 year old and over; Less than 15% of body surface area involvement Exclusion criteria: Pregnancy or Lactation; History of hypersensitivity to main or preservative ingredients of topical tacrolimus or clotrimazole; Serious skin or systemic diseases; History of consumption of topical or systemic antifungal medications in the recent 1 month before enrolling in study

Age

From **10 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

City

Shiraz

Postal code

Approval date

2014-02-24, 1392/12/05

Ethics committee reference number

CT-P-92-5510

Health conditions studied

1

Description of health condition studied

Pityriasis versicolor

ICD-10 code

B36.0

ICD-10 code description

Pityriasis versicolor

Primary outcomes

1

Description

Wood's lamp fluorescence

Timepoint

0, 3rd, and 5th week

Method of measurement

Wood's lamp radiation

2

Description

scale and hyperpigmentation grade

Timepoint

0, 3rd, and 5th week

Method of measurement

Physician global assessment

3

Description

Malassezia species positivity

Timepoint

0, 3rd and 5th weeks

Method of measurement

Direct KOH 10% smear

Secondary outcomes

1

Description

pruritus

Timepoint

0, 3rd, and 5th week

Method of measurement

Visual assessment scale

2

Description

Hypopigmentation

Timepoint

0, 3rd, and 5th week

Method of measurement

Physician global assessment

Intervention groups

1

Description

Intervention: Application of Tacrolimus 0.03% ointment two times a day for 21 days

Category

Treatment - Drugs

2**Description**

Control: Application of Clotrimazole 1% cream two times a day for 21 days

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person

Maryam Sadat Sadat

Street address

Dermatology clinic, Faghihi hospital, Zand St., Shiraz, Iran

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Research Council of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

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Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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Grant name**Grant code / Reference number**

91-01-01-5510

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

Yes

Title of funding source

Research Council of 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**

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Full name of responsible person

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Position

Resident

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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