Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

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)
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+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 versocolor

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
o, 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 centers

1

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
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Council of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
City
Shiraz
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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Sadat Sadat
Position
Resident
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Person responsible for updating data

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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