

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the Effect of Topical Liposomal Amphotericin B Compared to Clotrimazole Cream in the Treatment of Patients with Tinea Versicolor- single -Blind Clinical Trial.

Protocol summary

Study aim

Comparison of the efficacy of Liposomal Amphotericin B 0.4% gel and Clotrimazole 1% cream in the treatment of Tinea versicolor

Design

Phase 3, Parallel group, clinical trial, with consecutive sampling, including 44 patients, single blinded, computerized randomised with permuted blocks.

Settings and conduct

The study is conducted in the dermatology clinic of Shiraz University of Medical sciences. Group 1 Will apply Liposomal Amphotericin B 0.4% gel twice daily on the lesions. Group 2 will apply Clotrimazole 1% cream twice daily on the lesions. The patients are assessed at the beginning of treatment, then two weeks after treatment by Direct KOH 10% smear. The assessor is blinded to the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: between 15 to 50 years of age patients with Tinea versicolor: less than of 10% of body surface area. Exclusion criteria: pregnancy or lactation, history of hypersensitivity to topical Clotrimazole or Liposomal Amphotericin B, history of consumption of topical or systemic antifungal medication in the resent 1 month before enrolling study.

Intervention groups

Intervention group: Liposomal Amphotericin B 0.4% gel (Sina ampolish; Exir nano sina, Tehran, Iran) is applied twice daily. Control group: Clotrimazole 1% cream (Najo, Tehran, Iran) is applied twice daily.

Main outcome variables

Malassezia species positiveity, scale and hyperpigmentation on lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220221054082N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-17, 1400/12/26**

Update count: **0**

Registration date

2022-03-17, 1400/12/26

Registrant information

Name

Malek Khedri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 9049

Email address

m.khedri1399@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-07, 1400/12/16

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Topical Liposomal

Amphotericin B Compared to Clotrimazole Cream in the Treatment of Patients with Tinea Versicolor- single -Blind Clinical Trial.

Public title

Comparison of the efficacy of Liposomal Amphotericin B gel and Clotrimazole cream in treatment of Tinea versicolor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of Tinea versicolor and confirmation of diagnosis by Direct smear Patients of between 15 to 50 years old Less than 10% of body surface area

Exclusion criteria:

Pregnancy Lactation History of hypersensitivity to topical Clotrimazole or Liposomal Amphotericin B History of consumption of topical or systemic antifungal medication in the resent 1 month before enrolling study

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed by random allocation software and participants are randomly allocated in the intervention or control group. Randomization of 44 participants in the software is performed by permuted blocks includes eleven four blocks. The output of the software is a table that shows the number of each participant is allocated in the intervention or control group. This software is taken from the site Randomization.com.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because the drugs have different textures (gel vs. cream) the study is only investigator blinded. The assessment will be done by another clinician who is blinded to treatment. The patients will be instructed not to discuss the texture or labing of drugs.

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 Ave

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-02-03, 1399/11/15

Ethics committee reference number

IR.SUMS.MED.REC.1399.543

Health conditions studied

1

Description of health condition studied

Tinea Versicolor

ICD-10 code

B36.0

ICD-10 code description

Pityriasis versicolor

Primary outcomes

1

Description

Malassezia species positveity

Timepoint

0, 14th days

Method of measurement

Direct KOH 10% smear

2

Description

Scale and hyperpigmentation grade

Timepoint

0, 14th days

Method of measurement

Physician global assess

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Liposomal Amphotericin B 0.4% gel (Sina Ampholish, Exir, nano sina) is applied twice daily on the leasions, for 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: Clotrimazole 1% cream (Najo, Tehran, Iran) is applied twice daily on the leasions, for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person

Mehdi Ghahartars

Street address

Dermatology clinic, Shahid Faghihi hospital, Zand St., Shiraz City

City

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7134844119

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+98 71 3235 1087

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mghahar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeianzade

Street address

Research Council, Shiraz University of Medical sciences, Zand St., Shiraz City

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Grant name

Research grant of the Research Council of Shiraz University of Medical sciences

Grant code / Reference number

22355

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehdi Ghahartars

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Shiraz University of Medical Sciences

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Mehdi Ghahartars

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Malek Khedri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available