Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 leasions. Group 2 will apply Clotrimazole 1% cream twice daily on the leasions. 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 ampholish; 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 smaer 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 positiveity

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
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3235 1087
Email
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
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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
Street address
Dermatology clinic, Shahid Faghihi hospital, Zand St., Shiraz City
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3235 1087
Email
mghahar@sums.ac

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Ghahartars
Position
Associate Professor
Latest degree

Specialist

Other areas of specialty/work
Dermatology

Street address
Dermatology clinic, Shahid Faghihi hospital, Zand St., Shiraz t

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3235 1087

Email
mghahar@sums.ac

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Malek Khedri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3235 1087

Email
M.Khedri1399@gmail.com

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