

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of Fluconazole-NLC nano emulgel (0.5%) effect on Tinea versicolor in comparison with clotrimazole cream

#### Protocol summary

##### Study aim

Determination of fluconazole nanoemulgel effectiveness on Tinea versicolor in comparison with clotrimazole cream;

##### Design

Clinical trial (phase II) with control group, parallel, double blind and randomized on 60 patients. The patients will be randomized by choosing a sealed envelope containing intervention or control group code.

##### Settings and conduct

The patients in dermatology clinic, Boo-Ali hospital, Sari, will be divided to intervention or control group randomly, after clinical diagnosis. The diagnosis will be done based on clinical observation and positive smear test. The preparations will be packaged in similar tubes with definite code. Administrator, evaluator and patients are blind. The patients will receive medication 2 times daily for 8 weeks. The surface area of fungal lesion and clinical signs will evaluate at zero time, 2, 4 and 8 weeks after administration.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical observation of Tinea versicolor, above 5 years old and positive smear test. Exclusion criteria: The cases suffered from liver disorders, renal failure, diabetes, malignant disease, pregnancy, breast feeding, use of anti fungal drugs in recent one month, sore or damage in infected area

##### Intervention groups

Intervention group: The eligible patients will receive Fluconazole nanoemulgel 0.5% (prepared in Sari faculty of pharmacy) twice daily for 8 weeks. Control group: The eligible patients will receive Clotrimazole cream 1% (Pars Darou Co.) twice/day for 8 weeks.

##### Main outcome variables

Skin lesion area

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120707010203N10**  
Registration date: **2021-01-03, 1399/10/14**  
Registration timing: **retrospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

##### Registration date

2021-01-03, 1399/10/14

##### Registrant information

###### Name

Majid Saeedi

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1354 3082

###### Email address

msaeedi@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

2016-04-20, 1395/02/01

##### Actual recruitment end date

2017-09-22, 1396/06/31

##### Trial completion date

2017-09-22, 1396/06/31

##### Scientific title

Evaluation of Fluconazole-NLC nano emulgel (0.5%) effect on Tinea versicolor in comparison with

clotrimazole cream

#### Public title

Treatment effect of topical fluconazole nanoparticles on Tinea versicolor

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Clinical feature of Tinea versicolor Positive Smear test

##### Exclusion criteria:

Liver disease Nephrotic disorders Diabetes Malignant disease Pregnancy Breast feeding anti-fungal treatment in recent one months Sore or damage in infected area

#### Age

From **5 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **60**

Actual sample size reached: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants will be randomly assigned to two groups of intervention and control using simple randomization and patients will divide to intervention or control group based on their code. Randomization list will be prepared by online tool (<https://www.random.org/lists>) and sealed envelope will be used for concealment.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The fluconazole nano emulgel and clotrimazole cream will package in similar packaging. The preparations are similar in color and odor. The clinical researcher and patients will not be aware of the administered preparation.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

#### Street address

Deputy of Research and Technology building, Moallem sq., Sari, Iran

#### City

Sari

#### Province

Mazandaran

#### Postal code

4817844718

#### Approval date

2014-09-21, 1393/06/30

#### Ethics committee reference number

IR.MAZUMS.REC.93.1109

### 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

Skin lesion area

##### Timepoint

At the beginning of study (time zero) and 2, 4 and 8 weeks after treatment

##### Method of measurement

Clinical evaluation and smear test

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Fluconazole nanoparticles (NLC) emulgel 0.5%, will be prepared in faculty of pharmacy and will be formulated as nano-emulgel 0.5%. The preparations will be packaged and receive code label, after physicochemical and microbial control. The patients will receive Fluconazole nano-emulgel twice daily for 8 months. They will not receive any other medication in this period of time.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: Topical clotrimazole cream 1% (Pars Darou Co.) will be packaged in similar tubes to Fluconazole nano-emulgel and will be labeled by definite code. The patients will receive preparation twice/day for 8 months. They will not receive any other medication in this period of time.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Boo-Ali Hospital

**Full name of responsible person**

Prof. Zohreh Haj heydari

**Street address**

Dermatology clinic, Boo-Ali Hospital, Pasdaran Blvd., Sari, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4817844718

**Phone**

+98 11 3325 7230

**Fax**

+98 11 3354 3084

**Email**

zhajheydari@yahoo.com

**Web page address**

[https://isid.research.ac.ir/Zohreh\\_Hajheydari](https://isid.research.ac.ir/Zohreh_Hajheydari)

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Research and Technology deputy building, Moallem sq., Moallem street,

**City**

Sari

**Province**

Mazandaran

**Postal code**

4817844718

**Phone**

+98 11 3325 7230

**Fax**

+98 11 3325 7230

**Email**

msaeedi@mazums.ac.ir

**Web page address**

<https://profiles.mazums.ac.ir/Profile/msaeedi>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, 18th. Km of khazar road,

**City**

Sari

**Province**

Mazandaran

**Postal code**

4817844718

**Phone**

+98 11 3354 3084

**Fax**

+98 11 3354 3084

**Email**

msaeedi@mazums.ac.ir

**Web page address**

<https://profiles.mazums.ac.ir/Profile/msaeedi>

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy  
**Street address**  
Deputy of Research and Technology, Moallem Sq.  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4817844718  
**Phone**  
+98 11 3354 3081  
**Fax**  
+98 11 3354 3084  
**Email**  
msaeedi@mazums.ac.ir  
**Web page address**  
<https://profiles.mazums.ac.ir/Profile/msaeedi>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Majid Saeedi  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Faculty of Pharmacy, Mazandaran University of  
Medical Sciences, 18th. km of Khazar road, P.O.Box

48175-861  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4817844718  
**Phone**  
+98 11 3354 3082  
**Fax**  
+98 11 3354 3084  
**Email**  
MSaeedi@mazums.ac.ir  
**Web page address**  
<https://profiles.mazums.ac.ir/Profile/msaeedi>

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**  
it is secret

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available