Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effects of clotrimazole and clotrimazole nanogel in patients with skin complications caused by dermatophytosis.

Protocol summary

Study aim

The aim of this study is to compare the effect of clotrimazole and clotrimazole nanogel on skin lesions caused by dermatophytes and Malassezia species in patients referred to Imam Reza Hospital in Bojnourd in the year 1405-1406, in which we will compare the effect of commercially available clotrimazole and the synthesized nanogel.

Design

A clinical trial with a control group, with parallel groups, triple-blind, randomized, phase 3 on 124 patients. Block randomization was used for randomization.

Settings and conduct

Patients with skin lesions caused by dermatophyte and Malassezia fungi, referred to the dermatology clinic of Imam Reza Hospital in Bojnourd, who are enrolled in the study by a dermatologist.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: clinical diagnosis of dermatophyte, laboratory diagnosis of dermatophyte / Main exclusion criteria: pregnancy, immunocompromised patients, patients using immunosuppressive medications.

Intervention groups

After confirmation of fungal infection by the laboratory, patients are divided into two groups: · The first group is prescribed 1% commercially available ointment. · The second group is prescribed 1% clotrimazole nanogel prepared in this study. Subsequently, patients are asked to refer to the dermatology clinic at specified times after using the ointment and nanogel for evaluation of the lesion by a dermatologist. Subsequently, the dermatologist measures and compares the degree of improvement in relation to clotrimazole ointment and nanogel during consecutive patient visits, and ultimately, the efficacy of these two medications will be compared.

Main outcome variables

Photographic modality: Lesion extent, lesion thickness, lesion color

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260502069237N1**
Registration date: **2026-08-25, 1405/06/03**
Registration timing: **prospective**

Last update: **2026-08-25, 1405/06/03**
Update count: **0**

Registration date

2026-08-25, 1405/06/03

Registrant information

Name

Yaghoub Yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3222 0579

Email address

yazdaniyaghoub911@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-28, 1405/06/06

Expected recruitment end date

2027-08-28, 1406/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of clotrimazole and clotrimazole nanogel in patients with skin complications caused by dermatophytosis.

Public title
Comparison of the effect of clotrimazole nanogel and clotrimazole in the treatment of dermatophytosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of dermatophytosis Laboratory diagnosis of dermatophytosis
Exclusion criteria:
Pregnancy Patients with immunodeficiency Patients receiving immunosuppressive agents
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization was used for randomization. We will use blocks of size 4, consisting of 2 A's and 2 B's. The possible permutations are: AABB, ABAB, ABBA, BAAB, BABA, BBAA. We need 62 patients for A and 62 for B, totalling 124 patients. We need $124/4= 31$ blocks. To distribute the permutations as evenly as possible: $31/div 6= 5$ with a remainder of 1. So, 5 permutations will appear 5 times, and 1 permutations will appear 6 times.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After the preparation of clotrimazole nanogel and the purchase of clotrimazole ointment by the student researcher, each is packaged in completely identical and uniform containers. Prior to allocation to patients, block randomization is performed. Then, a professor who was involved in the preparation of the drug and does not participate in the conduct of the clinical trial divides the containers into two groups, A and B, based on the random sequence. The medications are randomly distributed among patients. Only that professor knows which group contains the clotrimazole nanogel and which contains the clotrimazole ointment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
North Khorasan University of Medical Sciences
Street address
No. 21, West Taleghani Street, Hejrat Street, 26 Hejrat Street, bojnourd town
City
Bojnourd
Province
North Khorasan
Postal code
9419678675
Approval date
2026-04-19, 1405/01/30
Ethics committee reference number
IR.NKUMS.REC.1405.008

Health conditions studied

1

Description of health condition studied
Dermatophytosis
ICD-10 code
L30.3
ICD-10 code description
Infective dermatitis

Primary outcomes

1

Description
extent of skin lesions caused by dermatophyte fungi
Timepoint
14 days
Method of measurement
A direct measurement protocol for lesion dimensions using a ruler is employed, which is described in various articles as a rapid and useful method. In this method, lesion length and width are measured, and the lesion area during treatment is calculated using the formula A = 0.73 × L × W.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the group treated with the 1% clotrimazole nanogel prepared in this study are assigned.
Category
Treatment - Drugs

2

Description
Control group: Patients in the group treated with 1% commercially available clotrimazole ointment are assigned.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Yaghoub Yazdani
Street address
No. 21, West Taleghani Street, Hejrat Street, 26 Hejrat Street, bojnourd town
City
Bojnourd
Province
North Khorasan
Postal code
9419678675
Phone
+98 996 299 6651
Email
yazdaniyaghoub911@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Abozar Nasiri Jahrodi
Street address
Laboratory Department ,Red Crescent Building, Khorramshahr Square, Bojnourd, Iran
City
Bojnourd
Province
North Khorasan
Postal code
۹۴۱۳۶۷۷۴۳۵
Phone
+98 58 3225 8038
Email
Nasir30a@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Yaghoub Yazdani
Position
Medical Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
No. 21, West Taleghani Street, Hejrat Street, 26 Hejrat Street, bojnourd town
City
Bojnourd
Province
North Khorasan
Postal code
9419678675
Phone
+98 58 3222 0579
Email
yazdaniyaghoub911@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Amir Amani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmaceutics
Street address

Shahriar street

City
Bojnourd

Province
North Khorasan

Postal code
9417694735

Phone
+98 58 3229 7157

Fax

Email
amani76@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Yaghoub Yazdani

Position
Medical Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
No. 21, West Taleghani Street, Hejrat Street, 26 Hejrat Street, Bojnourd town

City
Bojnourd

Province
North Khorasan

Postal code
9419678675

Phone
+98 58 3222 0579

Email
yazdaniyaghoub911@gmail.com

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
Due to the confidentiality of participants' data and images, the publication of patients' information and images is not possible.

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Not applicable

Title and more details about the data/document
The clinical study documents, including the informed consent form and the clinical study report. These documents provide information on the objectives and methods of conducting the study, interventions, outcome assessment, ethical considerations, confidentiality of information, the voluntary nature of participation, and the participants' right to withdraw from the study, in accordance with research ethics requirements and clinical trial registration standards.

When the data will become available and for how long
At least one year after the end of the study

To whom data/document is available
Yaghoub Yazdani Dr. Amir Amani Dr. Abozar Nasiri Jahrodi Dr. Amir Abbas Peymanfar

Under which criteria data/document could be used
Due to the confidentiality of patients' information and images, access to the data is not possible for anyone except the supervisors, the advisor, and the responsible student.

From where data/document is obtainable
Dr. Amir Amani Dr. Abozar Nasiri Jahrodi

What processes are involved for a request to access data/document
A message shall be sent to the email addresses of the advisors listed below, and one should await their response: amani76@gmail.com Nasir30a@gmail.com

Comments