

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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)

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+98 58 3222 0579

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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: $31/6 = 5$ 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 $A = 0.73 \times L \times W$. Secondary outcomes empty Intervention groups
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Abozar Nasiri Jahrodi

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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

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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