

Treatment of fungal infection in the ear, a comparison of topical treatments (clotrimazole vs terbinafine)

Submission date 02/09/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/09/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 17/09/2026	Condition category Ear, Nose and Throat	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title

Efficacy of topical terbinafine versus clotrimazole for the treatment of otomycosis: a randomized controlled trial

Study objectives

The aim of this study was to compare the clinical efficacy and safety of topical terbinafine versus topical clotrimazole 1% in patients with otomycosis.

Ethics approval required

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Ethics approval(s)

Approved 23/03/2022, Institutional Research Ethics Committee (CONBIOÉTICA-25-CEI-001-20180523) (Centro de Investigación y Docencia en Ciencias de la Salud, Universidad Autónoma de Sinaloa Eustaquio Buelna 91, Col Burocrata Culiacan Sin, Culiacan, 80060, Mexico; +52 (0) 6671023474; cei.cidocs.hc@uas.edu.mx), ref: 086

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Sequential

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Otomycosis

Interventions

Participants were allocated using computer-generated unrestricted simple randomization.

Before treatment initiation, all patients underwent meticulous microscopic debridement of the external auditory canal.

Participants assigned to the control group received topical 1% clotrimazole cream, whereas participants assigned to the intervention group received topical 1% terbinafine cream. In both groups, the medication was applied weekly until complete occlusion of the external auditory canal.

At the first follow-up visit, residual medication was removed, microscopic cleaning was repeated, and the same treatment was reapplied. Patients were followed weekly, the end of period follow up was 3 weeks.

Patients with persistent clinical evidence of otomycosis after completion of the assigned treatment follow up received rescue therapy with the alternative antifungal therapy, for example, patients in the clotrimazole arm received terbinafine and vice versa.

All participants received standardized instructions to keep the affected ear dry and avoid recognized predisposing factors throughout the study period.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Terbinafine, clotrimazole

Primary outcome(s)

1. Resolution of otomycosis measured using microscopy at 1, 2 and 3 weeks

Key secondary outcome(s)**Completion date**

15/07/2026

Eligibility**Key inclusion criteria**

1. Adults aged 18 years or older of either sex
2. Clinical diagnosis of otomycosis established by medical history, otomicroscopic examination, and mycological evaluation

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

99 Years

Sex

All

Total final enrolment

82

Key exclusion criteria

1. Patients with concomitant otologic diseases other than otomycosis
2. Allergy to study medications
3. Pregnancy
4. Inability to complete follow-up

Date of first enrolment

01/08/2022

Date of final enrolment

01/09/2025

Locations

Countries of recruitment

Mexico

Sponsor information

Organisation

Universidad Autónoma de Sinaloa

ROR

<https://ror.org/05g1mh260>

Funder(s)

Funder type**Funder Name**

Universidad Autónoma de Sinaloa

Alternative Name(s)

Autonomous University of Sinaloa, UAS

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Mexico

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available