

**FACTS** 



## Unknown

burden hinders global response



Delayed treatment can lead to

## amputation



Occurs most often in the so-called

## 'mycetoma belt'

between latitudes 15° S and 30° N

# **MYCETOMA**

# Developing safe, affordable treatments to prevent devastating disability

ne of the world's most neglected diseases, mycetoma is a slow-growing infection that destroys skin, muscle, and bone. Most likely transmitted after a thorn prick or cut allows fungi or bacteria from soil to enter the body, it mainly affects the feet and legs. Mycetoma occurs in multiple countries across the 'mycetoma belt' – stretching across five continents between the latitudes of 15° S and 30° N. **The fungal form** of mycetoma, known as eumycetoma, can cause severe deformities and disability, as well as social isolation due to the stigma associated with the disease.

#### The push for progress

Following advocacy from DNDi, the Mycetoma Research Center (MRC), and partners, the World Health Organization (WHO) added mycetoma to its list of neglected tropical diseases (NTDs) in 2016 – an important step in raising awareness of the disease and encouraging investment in research for diagnostics and treatments. In 2017, DNDi partnered with the MRC, a WHO collaborating centre in Khartoum, Sudan, and Japanese pharmaceutical company Eisai Co., Ltd., to begin enrolling patients in the first-ever randomized controlled clinical trial for eumycetoma treatment. Completed in 2021, the trial showed that the drugs fosravuconazole and itraconazole, combined with surgery, are both effective.

OUR GOAL IS NOW to develop improved treatments for mycetoma that can prevent devastating amputation and disability – and ensure access to current treatments for all people in need.

# Moving forward with a simpler, more affordable treatment

Initiated by DNDi and partners in 2017, the first-ever double-blind, randomized clinical trial for fungal mycetoma tested the efficacy of a weekly dose of fosravuconazole compared with twice-daily itraconazole in treating moderate-sized lesions in patients requiring surgery. Results published in *The Lancet Infectious Diseases* in November 2024 showed both treatments to be effective when combined with surgery, with fosravuconazole having practical advantages over itraconozole – including a lower pill burden, reduced risk of drug-drug interactions, and no need to administer the medication with food. Following consultation with WHO, DNDi and partners aim to obtain evidence on the use of fosravuconazole in other endemic countries to support a global treatment recommendation. In parallel, efforts continue to further improve patient care, including through early diagnosis and the identification of shorter treatments that can cure the disease without surgery.

### Conducting vital research to close knowledge gaps

A major barrier to developing new treatments for eumycetoma – and improving access to existing options – is a lack of data on the prevalence and impact of the disease. Our teams and partners are working to reduce these gaps and bolster international partnerships to establish transnational clinical studies and expand evidence-based approaches to mycetoma diagnosis, treatment, and prevention.





After noticing swelling in her left foot, her family worried she might have cancer but a series of biopsy tests confirmed the mass was not cancerous. She underwent surgery but the swelling continued.

Working with Bahir Dar University and Arba Minch University in Ethiopia, DNDi teams conducted visits in April 2024 to assess current medical practices and local treatment needs, collect existing epidemiological records, and establish partner networks in the country. This was followed by the initiation of a prospective study, including house-to-house visits by health extension workers in four regions to map the prevalence of disease and characteristics of the patient population, with suspected cases referred to the nearest health facility for case management.

In Senegal, retrospective data collection of mycetoma cases reported in medical and laboratory records across 14 sites began in July in partnership with Gaston Berger University and Cheikh Anta Diop University. In September, a similar exercise started in India, where data collection is ongoing across 23 sites in partnership with the Fungal Infections Study Forum.

In Kenya, DNDi worked with the African Institute for Health and Development to advance preparations for a social behavioural study in Turkana county. Kicking off in early 2025, the study is focusing on the treatment experiences and preferences of people affected by mycetoma in the highly endemic region, potentially shaping the design of future clinical trials there.

#### **Expanding partnerships in South Asia**

Although reported cases of mycetoma are greatest in sub-Saharan Africa, people have long been affected by the disease in South Asia – where it was once called 'Madura foot' after first being reported in Madurai, India in the mid-19th century.

Continuing efforts to expand research and access to care across the 'mycetoma belt', DNDi convened an expert meeting in New Delhi in September 2024 that brought together researchers from India, Indonesia, Nepal, and Pakistan to share local knowledge and evaluate options for the design of future clinical trials in South Asia. The 22 participants also agreed on the need to integrate treatment for eumycetoma into existing skin NTD programmes and develop a system for categorizing lesions as a first step towards developing a target product profile for new treatments.

## The heavy toll of conflict in Sudan

In early 2025, our long-time partners at the Mycetoma Research Center (MRC) in Khartoum learned that their entire facility had been looted, burned, and destroyed. Established in 1991 under the University of Khartoum, the MRC was the world's only dedicated research, treatment, and training centre for mycetoma and had served as a WHO collaborating centre for mycetoma and skin NTDs since 2015. The site was also home to clinical research conducted by DNDi and partners before it was forced to cease operations amidst growing insecurity.

It was hoped that the MRC could reopen its doors as soon as tensions settled in Khartoum. The tremendous loss for patients is staggering. Forty years of invaluable and irreplaceable medical data and biological samples were also lost in the destruction. We stand with our Sudanese colleagues and remain committed to doing all that we can to help restore access to care, reinitiate research and training, and enable the MRC to resume its vital role.

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Learn more: dndi.org/mycetoma