

Clinical trial for a better treatment for mycetoma starts in Sudan

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The first-ever double-blind, randomized clinical trial for an effective treatment for the severely neglected disease mycetoma has enrolled its first patient at the Mycetoma Research Centre (MRC) in Khartoum, Sudan.

Mycetoma is a chronic infection mainly of the foot that may spread to other parts of the body and causes severe deformity. Infection probably comes from the soil or animal dung, and it is thought that most patients are infected by walking barefoot and thus sustain minor cuts of thorns of the acacia tree.

The [disease](#) is endemic in tropical and subtropical areas of what is coined the 'mycetoma belt', which includes Venezuela, Chad, Ethiopia, India, Mauritania, Mexico, Senegal, Somalia, Sudan, and Yemen. Most countries are located between 30°N and 15°S, with Sudan the epicenter of the disease. It affects the poorest of the poor in poor remote communities. It has severe negative impacts on patients, families, communities and health authorities in endemic areas.

The trial seeks to compare the efficacy of a potential new treatment, fosravuconazole, to the existing therapy in people suffering from moderate eumycetoma, the fungal form of mycetoma. Today, the existing anti-fungal treatments for people suffering from eumycetoma only cure a fraction of patients, have a long treatment duration of a minimum of 12 months, are toxic, and cost an equivalent to more than a month's wage in the rural community. This means that the treatment is beyond the incomes of many rural poor and consequently affected patients often need an amputation to control the infection. In some the disease runs a fatal course.

"With the first patient enrolled now, what we have been working towards for the last ten years is at last a reality," said Dr Ahmed Fahal, Professor of Surgery at the University of Khartoum and Director of the MRC. "An effective, safe, affordable and

shorter-term curative [treatment](#) which is appropriate for rural settings is desperately needed for neglected patients suffering from mycetoma."

The study is being conducted by Drugs for Neglected Diseases *initiative* (DNDi) and the MRC together with Eisai Co., Ltd a Japanese pharmaceutical company which is providing the trial drug fosravuconazole. Since the intention to carry out the study was announced, the MRC has been preparing by following up national regulatory body approvals, strengthening laboratory functions and training of the MRC staff. Screening of potential patients began at the beginning of the month of May and the first patient was enrolled soon after.

"This important milestone comes one year after the landmark decision to include mycetoma in the list of the World Health Organization's official list of neglected tropical diseases," said Dr Nathalie Strub-Wourgaft, Medical Director, DNDi. "We are finally starting to roll the ball towards ending the neglect of [patients](#) suffering from mycetoma."

Provided by Drugs for Neglected Diseases Initiative

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