WHO revises advice on delamanid drug use in MDR-TB patients

A TB patient in a hospital in Guwahati. | Photo Credit: AP

Delamanid drug, approved for use in multidrug-resistant tuberculosis (MDR-TB) patients by the World Health Organisation in October 2014, did not show any statistically significant difference in successfully curing the disease or reducing the mortality rates compared with a dummy in a Phase III human clinical trial, WHO's position statement issued on January 15 says. However, the drug was found to be safe unlike many of the other second-line medicines used for MDR-TB treatment.

Though the trial did not confirm the efficacy findings of earlier studies, delamanid should be retained in country guidelines, national essential medicine lists and procurement options, says WHO. But the MDR-TB treatment algorithms "may need adjustment" in view of the Phase III trial results.

The 2014 interim guidance issued by the WHO on the use of the drug for treating MDR-TB patients was based on Phase IIb trial results and subject to review once Phase III trial results become available. A person is said to have MDR-TB when there is drug resistance to at least isoniazid and rifampicin, the two main first-line TB drugs.

In addition to optimised MDR-TB regimen, participants in the trial received either delamanid or a dummy for six months. At the end of 30 months of follow-up, 77.1% of MDR-TB patients who received delamanid drug were cured compared with 77.6% of those who received a placebo (dummy), and mortality was 5.3% in the delamanid group and 4.7% in the placebo group.

As a result, the WHO has advised all national TB programmes to include delamanid to longer MDR-TB regimen only when patients cannot tolerate or show resistance to certain second-line TB drugs. "When an effective and well-tolerated longer MDR-TB regimen can be otherwise composed, the addition of delamanid may not be warranted," the WHO says.

The conditions for using delamanid drug in patients remain the same — careful selection of patients who are likely to benefit, designing a longer MDR-TB regimen as receommended by the WHO, close monitoring of treatment response, and active TB drug-safety monitoring and management.

Astronauts on extended space travel missions would have significant bone and muscle complications.

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