Chagas Disease

An Emerging Public Health Concern

On April 28, 2015, FDA met with patients during one of FDA’s Patient-Focused Drug Development meetings to discuss patients’ concerns regarding their symptoms and treatment options for Chagas disease. These meetings are important as patients have the opportunity to convey their concerns about current medications and the types of medications they would like to see in the future.

No drugs have yet been shown to meet standards of safety and efficacy for FDA approval for the treatment of Chagas disease, but several potential treatments are in various stages of clinical investigation (see www.ClinicalTrials.gov). Two investigational drugs are available through the Center for Disease Control and Prevention (CDC), at a doctor’s request.

- Benznidazole
- Nifurtimox

What is Chagas Disease?

Chagas disease is a parasitic infection caused by the *Trypanosoma cruzi*. It primarily affects people living in rural parts of Latin America. Recent estimates are that there may be approximately 300,000 persons in the U.S. with Chagas disease who acquired the infection in areas where the disease is relatively common.¹

Most people with Chagas disease experience only mild or no symptoms and so they don’t realize that they are infected. Only rarely do infected persons experience life-threatening disease in the days to weeks after they are infected (early or acute phase). The infection persists for years and some persons go on to develop serious heart problems or gastrointestinal tract problems years or decades after they have been infected (late or chronic phase).

While the diagnosis can be made with blood tests in both early and late phases, many of those infected may never be diagnosed as they may have no symptoms or only very mild symptoms that resolve on their own.

Reference

How is Chagas Disease Transmitted?

In endemic areas, Chagas disease is most commonly spread from insects to humans. The Trypanosoma cruzi parasite is found in the feces of an infected blood-sucking triatomine bug. The parasite from the bug’s feces enters the body through an open wound or mucous membrane.

Other forms of transmission include

- Congenital transmission (mother-to-baby)
- Blood transfusion
- Organ transplant
- Accidental laboratory exposure
- Consuming contaminated food/water (Usually occurring in outbreaks, in endemic areas)

How is Chagas Disease diagnosed?

The diagnosis of Chagas disease can be made with blood tests. Many infected persons may not be diagnosed as they may have no symptoms or they had only very mild symptoms at the time of infection that resolved on their own.

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Neglected Tropical Disease Initiative Program

In 2010, FDA launched a Neglected Tropical Disease Initiative program to support the diagnosis, treatment, and prevention of neglected tropical diseases. This initiative was established to identify regulatory pathways and effective approaches to clinical trials to speed the development of new drugs and diagnostics for preventing and treating neglected tropical diseases such as Chagas Disease.

Additional Resources

- Chagas Disease Patient-Focused Drug Development meeting
- Information about Chagas’ Disease from CDC
- Neglected Tropical Disease Initiative