



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



Click [here](#) for more information from CDC about Chagas disease, including investigational treatment options.



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

¹Bern, C. and S.P. Montgomery, "An Estimate of the Burden of Chagas Disease in the United States," *Clinical Infectious Diseases*, 49:e52-54, 2009 (available at <http://cid.oxfordjournals.org/content/49/5/e52.full>)

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)

What are the Early and Late Phases of Chagas Disease?

Chagas disease has two phases an early (or acute) phase and a late (or chronic) phase.

- **Acute phase:** Lasts a few weeks to 2-3 months
- **Chronic phase:** Can last many years, or decades

Soon after becoming infected, during the early (acute) phase of disease, persons may experience mild, non-specific symptoms such as fevers, body aches, tiredness, and swelling around the site where the parasite entered the body.

Most people do not develop medical problems early after becoming infected. Very infrequently (generally less than 1% of the time) the early phase of the disease can be fatal.

Because the symptoms of early disease are usually mild and resolve without treatment, most people are not aware that they have been infected.

After the early phase of disease, the infection can persist for years. During the late or chronic phase, some persons (about one third) go on to develop serious heart problems or problems with the gastrointestinal tract over the years or decades after infection. Deaths from heart disease are common in this chronic phase and can occur suddenly. Persons with immune disorders, such as HIV or organ transplant patients, are at higher risk of having more severe disease.

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.

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](#)