

# Observational Pregnancy Safety Study of Women Exposed to Nifurtimox During Pregnancy to Describe the Risk of Pregnancy and Maternal Complications and Other Events of Interest on the Developing Fetus, Neonate, and Infant

**First published:** 09/04/2026

**Last updated:** 09/04/2026

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000884

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### Study ID

1000000884

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### DARWIN EU® study

No

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### Study countries

- Argentina
  - Bolivia, Plurinational State of
  - Chile
  - El Salvador
  - Germany
  - Guatemala
  - Honduras
  - Mexico
  - Spain
  - United States
  - Uruguay
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### **Study description**

This is an observational study in which data from women with Chagas disease who will take or have already taken nifurtimox during pregnancy and the impact on their babies are studied.

Chagas disease is an inflammatory, infectious disease caused by the parasite *Trypanosoma cruzi*. This parasite is mainly spread by insects called triatomine bug. If Chagas disease is left untreated, it can later cause e.g. serious heart and digestive problems.

Nifurtimox has been used for more than 50 years to treat Chagas disease in children and adults.

It is not recommended to be used during pregnancy as data from animal studies indicate that it may harm the baby. Currently, there are not enough data to know if this is also the case in humans.

In this study, researchers want to collect data on the safety of nifurtimox use in pregnant women. To do this, researchers will collect the following information:

- Birth defects (abnormal and problematic structures or functions, a child is born with)
- Pregnancy outcomes (like live birth, preterm birth, still birth/death of the

unborn baby, miscarriage, or abortion)

- Certain health problems of the child up to 12 months of age
- Certain health problems of the women experienced during pregnancy

The data will be collected from different sources including telephone calls with the women or their doctor, CRFs (case report forms) or from medical records

The researchers will compare the proportion of children with birth defects, pregnancy outcomes or certain health problems of the child or the women during pregnancy with available data on these outcomes in the general population.

The study will run for approximately 10 years.

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## Study status

Planned

## Research institutions and networks

### Institutions

**Bayer AG**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-  
contact@bayer.com

Study contact

[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)

**Primary lead investigator**

Amy Miller

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 24/01/2022

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**Study start date**

Planned: 30/06/2026

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**Date of final study report**

Planned: 01/12/2032

## Sources of funding

- Pharmaceutical company and other private sector

## Study protocol

[21944\\_LAMPIT\\_Protocol\\_v1.0\\_2022-01-24\\_for\\_publication.pdf](#) (507.43 KB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

## Other study registration identification numbers and links

NCT05477953

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

#### **Study design:**

The study will examine the effects of nifurtimox on fetuses, neonates and infants through 12 months of age who were exposed to nifurtimox in utero and maternal complications of pregnancy in women who were exposed to at least one dose of nifurtimox during pregnancy.

**Main study objective:**

To collect and describe:

- selected fetal/neonatal/infant outcomes (i.e., major congenital malformations (MCM), small for gestational age, and postnatal growth and development) at birth and through up to the first year of life of infants born to women exposed to nifurtimox during the defined pregnancy exposure window.
- pregnancy outcomes of interest (i.e., live birth, spontaneous abortions, stillbirths, elective abortions, and preterm births) and pregnancy complications in women with Chagas disease exposed to nifurtimox during the defined pregnancy exposure window.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Congenital Chagas disease

## Population studied

## **Short description of the study population**

Women with Chagas' disease who have been exposed to at least 1 dose of nifurtimox during the defined pregnancy exposure window and fetuses, neonates, and infants through 12 months of age who were exposed to at least one dose of nifurtimox in utero

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## **Special population of interest**

Pregnant women

# Study design details

## **Comparators**

Not applicable

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## **Outcomes**

- Pregnancy outcomes:
  - o Spontaneous abortion
  - o Elective abortion
  - o Fetal death/still birth
  - o Preterm delivery
  - o Live birth.
- MCM identified in the developing fetus, neonate or infant,
- Other events of interest identified in the developing neonate and infant,
  - o Hospitalizations
  - o Growth and development milestones as described by the Centers for Disease Control and Prevention (1)
  - o Neonatal or infant mortality
  - o Diagnosis of congenital Chagas' disease
- Maternal complications of pregnancy,

- o Premature rupture of membranes
  - o Preeclampsia
  - o Severe pregnancy induced hypertension
  - o Proteinuria
  - o Gestational diabetes
  - Measures of fetal growth deficiency (small for gestational age)
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### **Data analysis plan**

Statistical analyses will be of explorative and descriptive nature. The study is not intended to test pre-defined statistical hypotheses.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Non-interventional study](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown