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

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Study Planned

Administrative details

EU PAS number

EUPAS1000000884

Study ID

1000000884

DARWIN EU® study

No

Study countries

Argentina
Bolivia, Plurinational State of
Chile
El Salvador
Germany
Guatemala
Honduras
Mexico
Spain
United States
Uruguay

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 reprt 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.

Study status

Planned

Research institutions and networks

Institutions

Bayer AG

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

Study contact

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Primary lead investigator

Amy Miller

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/01/2022

Study start date
Planned: 30/06/2026

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

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

Study type:

Non-interventional study

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

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)

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown