POST AUTHORIZATION SAFETY STUDY OF FEXINIDAZOLE FOR HUMAN AFRICAN TRYPANOSOMIASIS : Analysis of real-life safety and effectiveness data on fexinidazole, collected by NSSCP & WHO as part of NSSCP activity as per WHO interim guidelines 2019 (FEXINC09395)

First published: 24/09/2020

Last updated: 01/07/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS37342

Study ID

48456

DARWIN EU® study

No

Study countries

- [ ] Anguilla
- [ ] Burkina Faso
- [ ] Cameroon
- [ ] Central African Republic
- [ ] Chad
- [ ] Congo
- [ ] Congo, The Democratic Republic of the
- [ ] Côte d’Ivoire
- [ ] Equatorial Guinea
- [ ] Gabon
- [ ] Ghana
- [ ] Guinea
- [ ] Mali
- [ ] Nigeria
- [ ] South Sudan
- [ ] Uganda

Study description

The PASS is based on the analysis of the data prospectively collected by the NSSCP/WHO PHP in selected sub-Saharan African countries as per WHO guidelines adopted by NSSCP.

This safety evaluation is considered as an additional Pharmacovigilance activity and is included in the Pharmacovigilance Plan as a Category 3 Post Authorization Safety Study (PASS).

The primary objective of this PASS is to assess the safety of fexinidazole in field conditions of use.

The secondary objective is to assess effectiveness of fexinidazole, in real life use by evaluating occurrence of relapse at 12 and 24 months of follow-up.

Study status

Ongoing

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Trial Transparency Team Team Contact-US@sanofi.com

Study contact

Contact-US@sanofi.com

Primary lead investigator

Trial Transparency Team Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2020

Actual: 08/12/2020

Study start date
Planned: 30/06/2025

Actual: 30/04/2025

Data analysis start date
Planned: 01/04/2025

Actual: 17/06/2025

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To evaluate safety of fexinidazole when used in field conditions of the National sleeping sickness control program.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Database analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

FEXINIDAZOLE

Anatomical Therapeutic Chemical (ATC) code

(P01CA03) fexinidazole

fexinidazole

Medical condition to be studied

African trypanosomiasis

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

Occurrence of any adverse events during the treatment period at end of treatment(EOT) and at end of hospitalization (EOH) if different of EOT and 6 months follow-up visit with special focus on AE included in the safety specifications in the RMP, Relapse occurrence according to relapse characteristics: date of occurrence, clinical or biological diagnosis, and rescue treatment.

Data analysis plan

Baseline demographic and clinical characteristics, treatment given as well as safety and effectiveness outcomes will be the object of descriptive analysis. Analysis will include treatment provided, dose, duration, compliance to instruction.
The safety analysis will include the number and percentage of patients with any adverse events, the stratifications by intensity (severity), seriousness and other characteristics, deaths during treatment and their description, pregnancy outcomes, as well as outcomes of children exposed in utero to fexinidazole, within two years following the birth.
Major AEs will be defined as those with intensity described as severe, very severe, or lethal, by the reporter.

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)

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

No