

# Risks of arrhythmias reporting with antiepileptics including Lamotrigine: a pharmacovigilance study in VigiBase®

**First published:** 03/02/2022

**Last updated:** 23/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS45559

---

### Study ID

45560

---

### DARWIN EU® study

No

---

### Study countries

 France

---

### Study status

Ongoing

## Research institutions and networks

# Institutions

## Toulouse University Hospital

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

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

Institution

## Contact details

### Study institution contact

François Montastruc [francois.montastruc@univ-tlse3.fr](mailto:francois.montastruc@univ-tlse3.fr)

Study contact

[francois.montastruc@univ-tlse3.fr](mailto:francois.montastruc@univ-tlse3.fr)

### Primary lead investigator

François Montastruc

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 02/02/2022

---

### Study start date

Actual: 02/02/2022

---

## Date of final study report

Planned: 08/04/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Study not financed

## Study protocol

[Study protocol\\_Risks of arrhythmias Antiepileptics.pdf](#) (232.26 KB)

## Regulatory

### Was the study required by a regulatory body?

No

---

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

The aim of this study is to compare the risks of arrhythmias with lamotrigine compared with other anti-epileptics.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Case/Non-case study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(N03AX09) lamotrigine

lamotrigine

---

**Medical condition to be studied**

Arrhythmia supraventricular

Conduction disorder

Ventricular arrhythmia

Cardiac arrest

## Population studied

### Age groups

- 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)
- 

### Estimated number of subjects

7000

## Study design details

### Outcomes

Risk of declaring an arrhythmia

---

### Data analysis plan

The data will be extracted from VigiBase(R). Using a case/non-case design, we will perform univariate logistic regression to estimate the odds ratios (RORs) with their 95% confidence intervals (CI). Reporting odds ratios (RORs) are the odds of exposure among reported cases of arrhythmias relative to the odds of exposure among reported non-cases. Sensitivity analyzes will be performed: First, restrict the analyzes to the reports of physicians. Second, carry out temporal analyzes every 5 years from 1994. Third, carry out analyzes just before the publication of the FDA alert on March 3, 2021. Fourth, analyzes will be performed separately on the four MedDRA high-level terms (HLT)

mentioned in the “case and non-case definitions” section. Fifth, the serious criteria will be analyzed compared to the non-serious ones. Finally, analyzes will be carried out by stratifying the data according to age (18 to 44, 45 to 64, 65 to 74 and over 75) or sex (male or female).

## 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.

#### **Conflicts of interest of investigators**

[EUPAS45559-45555.pdf](#) (111.63 KB)

---

#### **Composition of steering group and observers**

[EUPAS45559\\_steering\\_group.pdf](#) (232.26 KB)

---

#### **Signed code of conduct**

[ENCePPCoCAnnex3\\_DeclarationofcompliancewiththeENCePPCodeofConduct-signé-signé.pdf](#) (131.04 KB)

---

#### **Signed code of conduct checklist**

[ENCePPCoCAnnex2\\_ChecklistofCodeofConduct-signé.pdf](#) (197.16 KB)

---

## Data sources

## **Data sources (types)**

Other

---

### **Data sources (types), other**

Prospective patient-based data collection

## **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