ETUDE POST AUTORISATION NON INTERVENTIONNELLE EN VIE REELLE DE SECURITE DES PATIENTS TRAITES PAR BACLOFÈNE ZENTIVA (BACLOFÈNE) (baclosafe)

First published: 14/01/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS45165

Study ID

49247

DARWIN EU® study

No

Study countries

France

Study status

Ongoing

Research institutions and networks

Institutions

Hospice de Lyon

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Benjamin Rolland

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/05/2021

Actual: 12/05/2021

Study start date
Planned: 04/10/2022

Actual: 04/10/2022

Date of final study report
Planned: 30/10/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zentiva

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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Post authorization safety study on patient treated by zentiva baclofen for addictions

Main study objective:

incidence of SAEs related or not to Baclofene Zentiva in real life during one year follow up

Study drug and medical condition

Medicinal product name, other

baclofène

Medical condition to be studied

Dependence

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

1.000

Study design details

Outcomes

ncidence of SAEs related or not to Baclofene Zentiva in real life during one year follow up, incidence of AEs during one year association of AE and Demography or clinical data prescription in real life evolution of patients treated with Baclofene Zetniva SAEs related to drug according to investigator AEs related treatment stop specific situations with drugs

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Data analysis plan

incidenc will be calculated in patient/year with associated IC 95%

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)

Other

Data sources (types), other

Real life data based on sites in charge of addicted patients

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