Resistant Depression in France, description from the nationwide claims and hospitalization database (DIORAMA)

First published: 13/10/2017
Last updated: 24/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49894

EU PAS number
EUPAS20778

Study ID
49894

DARWIN EU® study
No

Study countries
France

Study description
Depression is a common mental illness, which concerns 4.8% of the French population and is associated with a high psychological, social and economic burden. In 15 to 30% of the depressive episodes, the depression becomes resistant to treatment but these estimates are not accurate since the notion of treatment-resistant depression (TDR) is difficult to define precisely. Conventionally, TRD involves depression that fails to improve adequately after the use of 2 AD (whether or not they are from different pharmacological class) at doses and durations that would normally be effective, administered to a patient believed to be adherent (3). Patients suffering from TRD experience a disproportionate burden of

illness with significant impairment, increased morbidity, and higher economic costs than those of a treatment responsive depression case (4). The global epidemiological situation and the clinical characteristics of TDR are thus poorly understood and require further study, especially in France. With the development of a new medication for the treatment of TRD, Janssen-France requests that the Bordeaux PharmacoEpi (BPE) platform, CIC Bordeaux CIC1401 of Bordeaux University, carries out a study in France to estimate the frequency of, the risk factors and the costs for TRD using the SNIIRAM nation-wide claims and hospital database.

Study status
Finalised

Research institution and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France
First published: 07/02/2023
Last updated
08/02/2023

Institution
Educational Institution
Hospital/Clinic/Other health care facility
Not-for-profit
ENCePP partner

Contact details

Study institution contact
Patrick Blin
Study contact

patrick.blin@u-bordeaux.fr

Primary lead investigator
Nicholas Moore
Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:
12/12/2016

Study start date
Actual:
30/06/2017

Data analysis start date
Planned:
30/09/2017
Actual:
30/09/2017

Date of final study report
Planned:
31/01/2019
Actual:
31/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

JANSSEN-FRANCE

Study protocol

DIORAMA-v1.4-20170828.pdf(987.21 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 topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology

Data collection methods:
Secondary data collection

Main study objective:
To estimate the prevalence and incidence of Treatment-Resistant Depression in the French population.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(N06A) ANTIDEPRESSANTS

Medical condition to be studied
Depression

Population studied

Short description of the study population
Patients aged 18 or older, resident in metropolitan France, with at least one antidepressants reimbursement in 2013, and without any diagnostic of psychotic disorders, Parkinson's disease, or dementia within the last two years preceding the initiation date, was reported in the study.

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)

Special population of interest
Hepatic impaired
Immunocompromised
Pregnant women
Renal impaired

Estimated number of subjects
1000000

Study design details

Data analysis plan
A Statistical Analysis Plan (SAP) was developed and validated by the Scientific Committee before the analysis. The statistical analysis was performed using the SAS® software (latest current version), following a detailed statistical analysis plan.The following analyses were performed:• A flow chart depicting the number of patients and sequences of treatment available in the database satisfying the inclusion criteria,• Description of baseline characteristics, comorbidities,• Description of the TDR episode,• Description of the TRD prevalence and incidence in 2012, 2013 and 2014, averaged per year and age- and sex-standardized to the French population,• Description of healthcare resources use during the TRD episode and during the follow-up period.

Documents

Study results
DIORAMA_ICPE_2019_v1.0-20190723 impVF2.pdf(5.53 MB)
poster DIORAMA Emois 2019 v1.0-20190312.pdf(4.64 MB)

Study publications
Bosco?Lévy P, Grelaud A, Blin P, Astruc B, Falissard B, Llorca PM, Bernard MA, …

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)

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