Use of Selincro® and impact on usual practice (USE-PACT)

First published: 15/12/2015

Last updated: 23/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11854

Study ID

49889

DARWIN EU® study

No

Study countries

☐ France

Study description

Selincro® (nalmefene) has obtained European market authorisation “for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and

who do not require immediate detoxification”. The French health authorities have requested an evaluation on real-life conditions of Selincro® use and its impact on morbidity. In response, a French prospective cohort including 1000 patients initiating Selincro® followed during 1 year using a random sample of general practitioners, psychiatrists, and physicians in specialised structures has been developed. The main objective is to evaluate the evolution of alcohol consumption at 1 year in patients initiating Selincro®. The secondaries are to describe prescribers characteristics, initial demographic, clinical, biological characteristics of patients, patient support, notably psychosocial, at start and during treatment, characteristics of Selincro® during the study period, the frequency of adverse effects during Selincro® treatment. Each participing physician should, during 4-month period, include in cohort all patients for whom he/she initiates Selincro® and fulfilling the eligibility criteria, and record in a non-inclusion register patients for whom Selincro® is initiated and not included in cohort. The physician will follow the patients with a clinical evaluation at 1, 3, 6, 9 and 12 months performed during usual follow-up consultations. In parallel, each patient will complete a self-administered questionnaire at the same points. Patients declared as lost-to-follow-up and, failing that, his/her general practitioner will be contacted in order to fill-out a “last known status questionnaire”. For patients who could not be reached, vital status will be investigated using the INSEE/INSERM centralised procedure defined by decree. The representativeness of the cohort will be evaluated by an analysis in a representative French health insurance database.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

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

Multiple centres: 180 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/07/2015

Actual: 14/10/2015

Study start date
Planned: 01/09/2015

Actual: 23/02/2016

Date of final study report
Planned: 01/12/2017

Actual: 10/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Lundbeck France

Regulatory

Was the study required by a regulatory body?

Yes

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate the evolution of alcohol consumption at one year in patients initiating Selincro® in usual practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N07BB05) nalmefene

nalmefene

Medical condition to be studied

Alcohol abuse

Population studied

Short description of the study population

Adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification initiated treatment with Selincro® (nalmefene).

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

1000

Study design details

Outcomes

The evolution of alcohol consumption at 1 year will be defined as the relative evolution of Total Alcohol Consumption (TAC) between inclusion and end of follow-up at 1 year.The TAC (g/day) is equal to the number of standard drinks consumed in previous week by patient multiplied by a factor of ten (one standard drink corresponding to about 10g of alcohol), then divided by 7 (days number of week). At the different times of follow-up (1, 3, 6, 9 and 12 months)

the evolution of alcohol consumption will be evaluated with respect to inclusion day in terms of: relative and absolute evolution of TAC and Heavy Drinking Days (HDD, number of days with a high consumption of alcohol), at least 70% reduction in TAC, change in the alcohol consumption risk level according to the WHO.

Data analysis plan

Statistical analysis will be performed after database lock using SAS® software.The representativeness of the cohort in terms of patient characteristics will be evaluated by an analysis in a representative French health insurance database, the EGB (Echantillon Généraliste de Bénéficiaires).Statistical analysis will provide a description of : the total population, and according to prescriber specialty, and pevious medicinal treatment, the treated patient characteristcs, the evolution in alcohol consumption, the follow-up, Selincro® treatment, and adverse events.

Data management

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