DRUG UTILISATION AND SAFETY STUDY OF MYSIMBA/CONTRAVE IN EUROPE AND THE UNITED STATES (NB-451 DUS)

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Study Planned

Administrative details

EU PAS number

EUPAS103743

Study ID

103744

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

United States

Study description

This is a drug utilization and safety study evaluating initiators of Mysimba in the EU and US using administrative health databases, patient registries, and drug registers. The EU study will report on data from national health databases (Sweden, Norway, Finland, Denmark) that have at least 750 new users of Mysimba from 2017 and beyond. The US portion of the study will report on data from the Arcadia Database. The primary objectives are to describe demographic and baseline characteristics of initiators and to evaluate patterns of Mysimba initiation and use, including use among group that are inconsistent with the labelled indication (e.g. age <18 years, no obesity/overweight indication, alternative doses), and (b) use incompatible with contradictions set out in the SmPC (e.g. uncontrolled hypertension, seizure disorders, renal failure, hepatic impairment, dependence/withdrawal of opioid, opioid agonist, alcohol/benzodiazepine withdrawal). Secondary objectives will describe the occurrence of adverse events of special interest (AESIs), and evaluate event occurrence for patient groups (any user, users compliant with SmPC, uses out of compliance). Secondary objectives will also assess duration of Mysimba use and will explore information related to titration scheme (e.g. change, alignment with SmPC), dose adjustments, reasons for treatment discontinuation, and adverse events leading to treatment discontinuation. Descriptive statistics will be performed to describe user groups and treatment duration and patterns. The incidence of AESIs will be estimated with rates and 95% confidence intervals based on person-time at risk. Reasons for treatment discontinuation will be explored using available recent (e.g. within 90 days before/after discontinuation) data prior to the end of known treatment discontinuation.

Study status

Planned

Research institutions and networks

Institutions

Currax Pharmaceuticals

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Michael Kyle

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2023

Actual: 01/03/2023

Study start date

Planned: 15/05/2023

Data analysis start date
Planned: 30/05/2024

Date of interim report, if expected
Planned: 16/12/2024

Date of final study report
Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Orexigen Therapeutics/Currax Pharmaceuticals LLC

Study protocol

Protocol NB-451_v4.0_7 Aug 23_FINAL.pdf (1.17 MB)

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)

Other study registration identification numbers and links

NB-451, EMEA/H/C/003687/MEA/003.11

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

Other

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

Adverse event reporting

Main study objective:

(1) To describe demographic and baseline characteristics of patients initiating use of Mysimba.

(2) To evaluate patterns of Mysimba initiation and use, including estimating the number and percentage of patients compliant and non-compliant with the SmPC.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

MYSIMBA

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

BUPROPION HYDROCHLORIDE

NALTREXONE HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(A08AA62) bupropion and naltrexone

bupropion and naltrexone

Medical condition to be studied

Overweight

Obesity

Population studied

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- 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

Hepatic impaired

Pregnant women

Renal impaired

Estimated number of subjects

15000

Study design details

Outcomes

Among Mysimba initiators, we will describe the population, treatment patterns, and assess (a) use inconsistent with labelled indication (e.g. age <18 years, no obesity/overweight indication, alternat doses), and (b) use incompatible with contradictions set out in the SmPC (e.g. uncontrolled hypertension, seizure disorders, renal failure, hepatic impairment, dependence/withdrawal of opioid). For Mysimba initiators, we will describe (a) incidence of adverse events of special interest overall, based on compliant use, and among subgroups (e.g. comorbidities, pregnant, history of substance abuse/dependencies). We will also describe (b) real-world drug use, e.g. titration schemes, dose adjustments, treatment discontinuations and reasons surrounding discontinuation, if available.

Data analysis plan

Data will be described for each country sample separately and on country samples with ≥750 patients (Sweden, Norway, Finland, Denmark, US).

Descriptive statistics will describe demographic and baseline variables and Mysimba treatment duration. Patient subgroups (e.g. comorbidities of interest, pregnant or lactating) and treatment pattern groups (e.g. compliant or non-compliant with the SmPC) will be described with counts and proportions. The incidence of adverse events of special interest (AESI) will be described overall and for subgroups using rates and person-time of exposure. For each type of AESI, we will estimate crude incidence rates and 95% confidence intervals. Treatment modifications (i.e. titration scheme changes, alternative maintenance doses to Mysimba 32mg/360mg, discontinuations) will be described using counts and proportions. Reasons for treatment discontinuations will be described based on data captured before the end of defined treatment discontinuation.

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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

NO LONGER EXISTS - Odense Pharmacoepidemiological Database

Danish registries (access/analysis)

Data source(s), other

- Drugs and Pregnancy, Finland
- Arcadia, United States
- NorPD

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

National health databases and drug registers in Sweden, Norway, Finland, and Denmark. The US portion of the study will use data from Arcadia databases.

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