Effectiveness of the Mysimba Physician Prescribing Checklist (PPC): Focus group to assess understanding, attitude, and behaviour for usage of the PPC and for key safety messages (NB-453 PPC focus groups)

First published: 01/03/2023

Last updated: 08/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS103748

Study ID

103749

DARWIN EU® study

No

Study countries

- ☐ Czechia
- ☐ Greece

Norway

Study description

This is a follow-up study to the NB-452 Physician Prescribing Checklist (PPC) survey study in which 71.3% (95%CI 64.9%, 77.1%) of Mysimba prescribers met the overall knowledge and understanding (KAU) criteria (primary outcome), which did not reach the pre-specified threshold of 85% for effectiveness of the PPC. Prior to developing a strategy for improving the awareness, usage and understanding of the Mysimba PPC, or making any modification to the risk minimisation strategy, it is necessary to conduct a root cause analysis of low awareness of the PPC as well as of incorrect responses to survey questions related to knowledge and understanding of selected key safety messages. This focus group study will be conducted to help determine the adequacy of the Mysimba PPC, and potentially guide strategies to improve the understanding of key safety messages described in the EU RMP for Mysimba.

Study status

Finalised

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: 14/12/2022

Actual: 14/12/2022

Study start date

Planned: 31/03/2023

Actual: 31/03/2023

Data analysis start date

Planned: 30/06/2023

Actual: 30/06/2023

Date of final study report

Planned: 30/09/2023

Actual: 23/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Orexigen Therapeutics/Currax Pharmaceuticals LLC

Study protocol

NB-453 Focus Group Protocol_05 DEC 2022_FINAL.pdf (512.8 KB)

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-453, EMEA/H/C/003687/II/0054

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To identify factors that could explain the low awareness and usage of the PPC seen in Study NB-452 as well as the inadequate responses to selected questions on key safety messages.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Online focus groups

Study drug and medical condition

Name of medicine

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

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

24

Study design details

Outcomes

Among Mysimba prescribers, the study aims to determine prescribers' awareness and usage of the PPC, and to understand prescribers' attitudes and agreement with the key safety messages in the PPC. Based on feedback obtained during conduct of focus groups, it will be determined whether changes to the PPC are necessary to improve awareness and understanding of key safety messages.

Data analysis plan

As qualitative research, there are no endpoints. Instead, themes will be sought with the aim of saturation (i.e. no more new themes emerge from discussions). Thematic analysis will be used, which involves searching across discussion verbatim and notes in order to identify, organize, describe repeated patterns. The verbatim of the focus group discussions will be transcribed and analyzed along with field notes constructed by the moderator and assistant moderator, and any notes extracted from the debriefing meeting. Coding will be conducted using a qualitative data analysis software program. Analysis will include systematic coding using constant comparison analysis. Codes will be reviewed to identify themes, opinions, and beliefs that are recurrent (referred to as nodes). Coding will be deductive (pre-set coding scheme, based on hypotheses regarding less well understood safety messages) and inductive (nodes will be generated while examining data). Significant nodes will be grouped.

Documents

Study results

nb-453-csr_23 OCT 23.pdf (901.13 KB)

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

Mysimba-prescribing physicians in 3 countries will be invited to participate in online focus groups.

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