Prescriber survey to evaluate the awareness to risk minimisation measures for mitoxantrone-containing medicinal products in the treatment of patients with highly active relapsing multiple sclerosis associated with rapidly evolving disability

First published: 05/11/2019

Last updated: 04/10/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS32142

Study ID

43380

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Norway
- [ ] Spain
- [ ] Sweden

Study description

Mitoxantrone is indicated for the treatment of numerous malignancies, such as metastatic breast cancer, non-Hodgkin’s lymphoma and acute myeloid leukaemia in adults. Mitoxantrone is also indicated for the treatment of patients with highly active relapsing multiple sclerosis (MS) associated with rapidly evolving disability, where no alternative therapeutic options exist. In this post-authorisation safety study (PASS) a survey will be used to obtain information on the understanding, knowledge and self-declared behaviour of treating (or intending to treat) neurologists on the screening and monitoring requirement for highly active relapsing MS patients, to minimise the cardiotoxic and malignancy risk associated with the use of mitoxantrone.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

- [ ] United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Massoud Toussi massoud.toussi@iqvia.com

Study contact

massoud.toussi@iqvia.com

Primary lead investigator

Massoud Toussi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/09/2019

Actual: 23/09/2019

Study start date

Planned: 31/08/2021

Actual: 03/05/2021

Data analysis start date

Planned: 10/08/2021

Date of final study report
Planned: 13/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MYLAN Inc

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:

Effectiveness study (incl. comparative)

Main study objective:

The objective of this study is to evaluate the awareness of the treating (or intending to treat) neurologists on risk minimization measures (RMMs) for patients with highly active relapsing MS associated with rapidly evolving disability, to minimize the cardiotoxic and malignancy risk associated with the use of mitoxantrone detailed in the EMs.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

MITOXANTRONE

Medical condition to be studied

Relapsing multiple sclerosis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

98

Study design details

Data analysis plan

Continuous variables will be described by their number (of valid cases), mean, standard deviation, and median, Q1, Q3, minimum and maximum. Categorical variables will be described as the total number and relative percentage per category. CI of 95% will be evaluated, when relevant. Results will be weighted based on the real number of neurologists in each country as mentioned in OneKey lists. The proportions of correct and appropriate answers to selected questions asked in the questionnaire will be expressed among neurologists who provided answers to those questions. The endpoint will be assessed overall, by country and by neurologists. The neurologists' participation in the survey will be examined in several ways: 1) response rate, 2) refusal rate, 3) contact rate, 4) cooperation rate. The assessment of the success of the RMMs will be considered for each of the three outcomes awareness, self-declared behavior, and knowledge.

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

The survey is a primary data collection conducted through a questionnaire administered by web. Neurologists will be identified from OneKey lists (IQVIA). The lists are representative of the prescriber’s population in the countries selected. A screening question will check whether the neurologist works with mitoxantrone in patients having highly active relapsing MS.

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