A European Study of the Effectiveness of Risk Minimisation Measures for Fenfluramine in Dravet Syndrome (TAPESTRY eRMM)

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48742

EU PAS number
EUPAS48741

Study ID
48742

DARWIN EU® study
No

Study countries
Austria
Denmark
France
Germany
Italy
Spain
United Kingdom

Study description
This observational study will assess the effect of additional risk minimisation measures by describing the awareness, knowledge, and compliance of fenfluramine prescribers to the

physician-specific educational material, as well as the distribution of the patient/carer educational material by the physicians.

Study status
Ongoing

Contact details

Study institution contact
Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.
Study contact

clinicaltrials@ucb.com
Primary lead investigator
Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
27/06/2022

Study start date
Actual:
30/08/2022

Date of final study report
Planned:
11/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zogenix International Ltd., UCB BioSciences 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)

Other study registration identification numbers and links

EP0220,ZX008-2104

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Other

If ‘other’, further details on the scope of the study
Assess the awareness, knowledge, and the self-reported compliance of physicians routinely prescribing fenfluramine with the recommendations provided the educational material on echocardiogram follow-up

Main study objective:
Assess the awareness and knowledge of physicians routinely prescribing fenfluramine regarding the educational material on echocardiogram follow-up Assess the self-reported compliance of physicians routinely prescribing fenfluramine with the recommendations

provided in the educational material on echocardiogram follow-up

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(N03AX26) fenfluramine

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)

Estimated number of subjects
100

Study design details

Outcomes
Variables associated with 1) the awareness and knowledge of physicians routinely prescribing fenfluramine regarding the educational material on echocardiogram follow-up and 2) the self-reported compliance of physicians routinely prescribing fenfluramine with the recommendations provided in the educational material on echocardiogram follow-up will be collected. Variables associated with 1) the physician-reported distribution of educational material to patients/carers by physicians routinely prescribing fenfluramine and 2) the awareness, knowledge and self-reported compliance of physicians routinely prescribing fenfluramine regarding the physician-specific educational material on prevention of off-label use for weight management will be collected.

Data analysis plan
All assessment data will be summarised using descriptive techniques. Results will be presented overall and at the country level. The proportion of responding and non-responding physicians will be provided for each question in the questionnaire. The response option ‘I don’t know’ or ‘I don’t recall’ will be considered a neutral response and will still be included in the denominator for the analysis. Continuous variables will be described with summary statistics such as the total number of observations in the sample

(i.e. n), mean, standard deviation, median, first quartile, third quartile, minimum, and maximum. Categorical variables will be described as the total number and relative percentage per category. Percentages will be calculated using the specified denominator in the table. Confidence intervals of 95% will be calculated when relevant.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective completion of survey by physicians

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