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

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. clinicaltrials@ucb.com

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

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

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

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