A phase IV, non-interventional, post--marketing registry study on the use of Tracydal® (tranylcypromine) for the treatment of treatment-resistant depression in the Netherlands

First published: 16/06/2016

Last updated: 27/06/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS13809

Study ID

30303

DARWIN EU® study

No

Study countries

Netherlands

Study description

During the registration procedure for Tracydal® market approval, a commitment was made by the applicant to set-up a post-marketing registry study to assess the effectiveness of risk minimisation measures for Tracydal® and to monitor the use of tranylcypromine for the treatment of treatment-resistant depression in the Netherlands.The primary objective is to evaluate if the educational material provided to patients and psychiatrists will be used and appreciated. This will be done by monitoring and evaluating the occurrence of adverse drug events related to hypertensive crisis. The secondary objective is to monitor the overall occurrence of adverse drug events, with the emphasis on: occurrence of convulsion, orthostatic hypotension and serotonin syndrome, exposure during pregnancy, suicidal ideation/behavior and acute toxicity, withdrawal reactions (including delirium) and to assess information related to exposure during human milk, exposure to children and adolescents (<18 years old), renal toxicity. Another secondary objective for the study is to evaluate efficacy based on assessment of depression and social functioning used in standard practice by psychiatrist for diagnosis and efficacy measurements.

Study status

Ongoing

Research institutions and networks

Institutions

DADA Consultancy

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Institution

Contact details

Study institution contact

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Study contact

pass@dada.nl

Primary lead investigator

Gaby Beckers

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/12/2011

Actual: 02/12/2011

Study start date

Planned: 17/10/2016

Actual: 16/11/2016

Data analysis start date

Planned: 15/11/2018

Date of interim report, if expected

Planned: 16/02/2018

Actual: 14/02/2018

Date of final study report
Planned: 16/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daleco Pharma B.V.

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To assess the effectiveness of risk minimisation measures for Tracydal® and to monitor the use of tranylcypromine for the treatment of treatment-resistant depression in the Netherlands.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Medicinal product name, other

Tracydal

Medical condition to be studied

Depression

Population studied

Age groups

- 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)

Estimated number of subjects

229

Study design details

Outcomes

The primary endpoint is the number of occurrences recorded that would indicate non-regard to the educational material provided to patients. This is the incidence of preventable adverse drug events related to the important identified risks as identified in the RMP, the risk being hypertensive crisis. The secondary endpoints are:1. Overall occurrence of adverse drug events2. Percentage change in the value of severity of depression scale and response based upon the validated response criteria for the rating scale utilized. 3. Percentage change in the value of social functioning scale and response based upon the validated response criteria for the rating scale utilized.

Data analysis plan

All data will be presented in terms of descriptive statistics and presented in tabular format. Exploratory analysis will be focusing on Spearman Correlations analysis to be able to determine whether any factors have a significant correlation with the frequency of adverse events, evaluations based on depression or social functioning scales. Factors to be analysed will be described

and listed in the statistical analysis plan.

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 patient-based data collection, Exposure registry

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