

# 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

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### Study ID

30303

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### DARWIN EU® study

No

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### Study countries

 Netherlands

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## 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.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

[DADA Consultancy](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

## Contact details

### Study institution contact

Gaby Beckers pass@dada.nl

Study contact

[pass@dada.nl](mailto: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

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### Study start date

Planned: 17/10/2016

Actual: 16/11/2016

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### Data analysis start date

Planned: 15/11/2018

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### Date of interim report, if expected

Planned: 16/02/2018

Actual: 14/02/2018

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### **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

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### **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

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**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

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**Non-interventional study design, other**

Prescription event monitoring

## Study drug and medical condition

**Medicinal product name, other**

Tracydal

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**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)
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## **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 events 2. 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.

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## **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](#)

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### 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No