

# Retrospective non-interventional study of stiripentol use in Dravet patients in the USA (Retrospective US Study - STP228)

**First published:** 04/10/2023

**Last updated:** 27/08/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS107005

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### Study ID

107006

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

This is a retrospective, non-interventional, observational, multicentre chart review study to be conducted in patients who have a diagnosis of Dravet syndrome and received stiripentol for a minimum of 3 months. The goal of the study is to understand the management of Dravet patients who received stiripentol in the United States of America after the drug was made available. US sites where investigators are treating or have treated patients with Dravet syndrome will be selected, and investigators will be neurologists and epileptologists who have initiated stiripentol therapy in Dravet patients since 21-Aug-2018. This study will aim to collect data from 100 patients records from approximately 10 sites in the US.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

Multiple centres: 10 centres involved in the study

## Contact details

### **Study institution contact**

Elaine WIRRELL [wirrell.elaine@mayo.edu](mailto:wirrell.elaine@mayo.edu)

**Study contact**

[wirrell.elaine@mayo.edu](mailto:wirrell.elaine@mayo.edu)

### **Primary lead investigator**

Elaine WIRRELL

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 08/03/2022

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### **Study start date**

Actual: 09/05/2022

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### **Data analysis start date**

Planned: 01/10/2023

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### **Date of final study report**

Planned: 01/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

BIOCODEX GENTILLY

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

The goal of the study is to understand the management of Dravet patients who received stiripentol in the United States after the drug was made available. The main study objectives are to:

- Characterize the treatment patterns of stiripentol in the US following marketing authorization
- Evaluate the efficacy of stiripentol treatment on seizure frequency
- Estimate the impact of stiripentol

### Study drug and medical condition

**Medicinal product name**

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

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**Anatomical Therapeutic Chemical (ATC) code**  
(N03AX17) stiripentol  
stiripentol

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**Medical condition to be studied**  
Severe myoclonic epilepsy of infancy

## Population studied

### Age groups

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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**Estimated number of subjects**  
100

## Study design details

### Outcomes

Frequency decreased of bilateral convulsive, Frequency of status epilepticus

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### **Data analysis plan**

Statistical analyses will be descriptive

## Documents

### **Study publications**

[De Liso P, Chemaly N, Laschet J, Barnerias C, Hully M, Leunen D, Desguerre I, C...](#)

[Thanh TN, Chiron C, Dellatolas G, Rey E, Pons G, Vincent J, Dulac O. Long-term ...](#)

[Chiron C. Stiripentol for the treatment of seizures associated with Dravet synd...](#)

[Myers KA, Lightfoot P, Patil SG, Cross JH, Scheffer IE. Stiripentol efficacy an...](#)

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## 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**

Patient charts records

## 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