Rapid Data Analysis – Tolperisone drug utilisation

First published: 26/03/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS40290

Study ID

40291

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This was a study of drug utilisation of tolperisone in Germany with yearly data on number of patients with a prescription, number of prescriptions, number of new users, and indication for treatment (classified as 'in-label' in accordance

with new label) between January 2009 and June 2020. Results were stratified by gender, age group and type of practice.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Chantal Quinten chantal.quinten@ema.europa.eu

Study contact

chantal.quinten@ema.europa.eu

Primary lead investigator

Chantal Quinten

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/02/2020

Actual: 03/02/2020

Study start date
Planned: 08/01/2021

Actual: 08/01/2021

Data analysis start date
Planned: 08/01/2021

Actual: 08/01/2021

Date of final study report
Planned: 15/02/2021

Actual: 15/02/2021

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To study yearly prescribing of tolperisone including indications for use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

TOLPERISONE

Population studied

Short description of the study population

Patients receiving at least one prescription with Tolperisone 50 mg or 150 mg film-coated tablets.

Only patients with a minimum observation time of 365 days over the period 2009-2020 were eligible to be included in the study which resulted in extending the observation period to 1 January 2008 to assess eligbility.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

20000

Study design details

Data analysis plan

Descriptive study.

Documents

Study results

EMA data analysis - tolperisone - report on results for publication.pdf (277.36 KB)

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 source(s), other

IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

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