Rapid Data Analysis – Tolperisone drug utilisation

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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

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Study contact

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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

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

Study topic:

Study type:

TOLPERISONE

Population studied

Short description of the study population

Human medicinal product

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 eligibility.

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

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

Unknown			
Check completer	ness		
Unknown			

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No