Drug Utilization Study (DUS) and post authorization safety study (PASS) on the fixed combination Tramadol-Dexketoprofen (DKP-TRAM)

First published: 26/05/2021

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24858

Study ID

46777

DARWIN EU® study

No

Study countries

Italy

Spain

Study description

To evaluate pattern of prescription of DKP-TRAM and assess the risk of adverse events in DKP-TRAM vs. Tramadol monotherapy users with a special focus on patients 75 year-old and over

Study status

Finalised

Research institutions and networks

Institutions

Health Search, Italian College of General Practicioners

Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

Multiple centres: 2 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lapi Francesco

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/06/2018

Study start date

Planned: 01/01/2017

Actual: 01/01/2017

Data analysis start date

Planned: 01/01/2017

Actual: 01/01/2017

Date of interim report, if expected

Planned: 31/01/2021

Actual: 31/01/2021

Date of final study report

Planned: 10/08/2021

Actual: 10/08/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Menarini International Operations Luxembourg

Study protocol

protocollo finale versione 1.pdf (5.81 MB)

protocollo finale versione 3.pdf (648.67 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate pattern of drug use (i.e. indication, dosage and duration) of DKP-TRAM

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post authorization safety study (PASS)

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02AJ14) tramadol and dexketoprofen

tramadol and dexketoprofen

(N02AJ13) tramadol and paracetamol

tramadol and paracetamol

(N02AX02) tramadol

tramadol

Medical condition to be studied

Pain

Population studied

Short description of the study population

All patients aged 18 years or older being registered in the databases between January 1, 2017 and December 31, 2018.

Inclusion criteria

Primary objectives (drug utilisation): all patients aged 18 years or older with at least 1-year medical history in the database and prescribed with DKP-TRAM coded via the Anatomical Therapeutic Chemical (ATC) classification system (ATC: N02AJ14) will be identified. For each patient, the date of the first prescription of DKP-TRAM being registered in the study period will be the index date.

Secondary objectives (comparative safety): all patients aged 18 years or older and newly prescribed with DKP-TRAM (ATC: N02AJ14) or tramadol (ATC: N02AX02) or tramadol-paracetamol (ATC: N02AJ13) will be identified. For each patient, the date of the first DKP-TRAM or tramadol (including tramadol-

paracetamol)prescription in the study period will be the index date.

Exclusion criteria
Primary objectives (drug utilisation): Patients 1) with missing data on age or gender, 2) with less than 1-year medical history in the database, 3) aged 17 years or younger.
Secondary objectives (comparative safety): Patients 1) with missing data on age or gender, 2) with less than 1-year medical history in the database, 3) aged 17 years or younger, 4) being prescribed with tramadol (or tramadol-paracetamol) in the entire period (up to 1998 and 2010 for HSD and SIDIAP, respectively) preceding the index date.

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

2.828

Study design details

Outcomes

Indication, duration and dosage of medications use, demographic factors, life style factors, comorbidities, co-medications and prescriber type (GP or specialist). Adverse events (e.g. nausea, vomiting, diarrhoea, vertigo, allucinations and somnolence) in incident users of DKP-TRAM vs. incident user

of Tramadol as monotherapy (including fixed combination tramadol-paracetamol), with a special focus on patients 75 year-old and over.

Data analysis plan

Primary objectives: Crude age- and sex- standardised incidence rate (IR) of DKP-TRAM use will be computed, along with descriptive analysis concerning indication, duration and dosage. Continuous variables will be describe as mean with standard deviation or median with interquartile range. Categorical variables will be described as N and percentages. Secondary objectives: The risk of AEs in users of DKP-TRAM will be compared with the risk of AEs in users of tramadol as monotherapy by estimating HR with related 95% confidence intervals (CI) through Cox regression model. Tramadol monotherapy users will be the reference category. All these analysis will be updated with information on data entering the databases in 2018.

Documents

Study results

FINAL_PASS_Menarini_DKP_TRAM_final_report_V04__Clean 14.01.22.pdf (1.39 MB)

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)

Health Search/IQVIA Health Longitudinal Patient Database

The Information System for Research in Primary Care (SIDIAP)

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