Impact of EU label changes for systemic diclofenac products: post-referral prescribing trends

First published: 30/05/2018

Last updated: 17/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24089

Study ID

33662

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Netherlands
- [ ] United Kingdom

Study description

To evaluate the impact of the risk minimisation measures implemented in 2013 to manage the cardiovascular risks of systemic diclofenac containing medicinal products authorised in the European Union (EU) in clinical practice

Study status

Finalised

Research institutions and networks

Institutions

MEMO Research, University of Dundee

United Kingdom (Northern Ireland)

First published: 12/05/2010

Last updated: 17/05/2024

Institution | Educational Institution | Not-for-profit | ENCePP partner

UCL School of Pharmacy, University College London

United Kingdom

First published: 11/03/2010

Last updated: 21/04/2015

Institution | Educational Institution | ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas MacDonald

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/09/2017

Actual: 06/09/2017

Study start date
Planned: 01/07/2018

Actual: 01/07/2018

Date of final study report
Planned: 06/01/2019

Actual: 06/01/2019

Sources of funding

- EMA

Study protocol

final Study Protocol Diclofenac_130318 (002).pdf(255.96 KB)

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 type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Three main objectives as follows: To determine prescription patterns of diclofenac containing products. To determine prescribers compliance with cardiovascular contraindications and risk factors. To determine prescription patterns of alternative medicines prescribed in patient where diclofenac has previously been prescribed.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Population-based longitudinal study, Time series analysis

Study drug and medical condition

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

DICLOFENAC POTASSIUM

DICLOFENAC SODIUM

Population studied

Short description of the study population

All patients registered within each data source at any time during the study period who discontinued diclofenac-containing medical products covering the regulatory intervention in June 2013.

Age groups

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

1000000

Study design details

Data analysis plan

In order to determine prescription patterns of diclofenac containing product, prescribers' compliance with cardiovascular contra-indications and risk factors and prescription patterns of alternative medicines prescribed in patients where diclofenac has previously been prescribed, the proposed primary analysis will use interrupted time series regression to fit time trends to each series of time period data (based on quarterly time periods)for each country.Using regression modelling we will evaluate:(I)the baseline slope before the regulatory intervention time point (ii)the change in slope from the baseline trend to the post-intervention trend, and (iii) the immediate change associated with the regulatory intervention time point. The choice of analytical technique will be decided based on visual inspection of the data. The analysis will be done by data source initially, and only pooled if the statistical models do not differ significantly between data sources.

Documents

Study results

Impact_diclofenac_prescribing_abstracts.pdf(190.34 KB)

Study, other information

Diclofenac_Abstract_ISPE submission_1_050319.pdf(289.33 KB)

Morales_et_al-2020-Pharmacoepidemiology_and_Drug_Safety (2) (002).pdf(2.54 MB)

Study publications

Morales DR, Morant SV, MacDonald TM, Mackenzie IS, Doney ASF, Mitchell L, Benni...

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Declaration of Interests.pdf(779.42 KB)

TMM_ENCePP Declaration of Interest_300518.pdf(911.34 KB)

Composition of steering group and observers

Steering Group_Diclofenac_May18v2.pdf(9.98 KB)

Signed code of conduct

2018-0050-Declaration of compliance_ENCePP CoC_EUPAS24089.pdf(238.33 KB)

Signed code of conduct checklist

2018-0050-Checklist ENCePP CoC_EUPAS24089.pdf(1.71 MB)

Signed checklist for study protocols

2018-0050-ENCePP checklist Study Protocols_EUPAS24089.pdf(1.98 MB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

PHARMO Data Network

Data source(s), other

eDRIS

Data sources (types)

Drug dispensing/prescription data

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