Usage Patterns of Selected Systemic NSAIDs (Including Diclofenac): A Retrospective Cohort Study

First published: 12/08/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10649

Study ID

18103

DARWIN EU® study

No

Study countries

- [ ] United Kingdom
- [ ] United States

Study description

This will be a non-interventional, descriptive, retrospective drug utilization study, using a cohort design, of users of selected systemic NSAIDs. The objective is to describe the usage pattern of selected systemic NSAIDs including diclofenac using the most recent information available from select population-based health care automated databases in Europe and North America. The study aims to accomplish the following:• Describe demographic characteristics, specific comorbidities, selected comedications, and selected potential indications for use among patients treated with selected systemic NSAIDs (including diclofenac)• Describe treatment patterns, including dose, duration of treatment, and switching patterns, among patients treated with selected systemic NSAIDs (including diclofenac)

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/03/2015

Actual: 13/08/2015

Study start date
Planned: 05/10/2015

Actual: 13/08/2015

Data analysis start date
Planned: 26/10/2015

Date of final study report
Planned: 16/03/2016

Actual: 06/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma

Study protocol

CVOL458A2001_v00_final protocol_redacted.pdf (453.88 KB)

vol458a2001--protocol-or-amendment_redacted.pdf (921.81 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CVOL458A2001

Methodological aspects

Study type

Study type list

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 accomplish the following: Describe demographic characteristics, specific comorbidities, selected comedications, and selected potential indications for use among patients treated with selected systemic NSAIDs (including diclofenac),Describe treatment patterns, including dose, duration of treatment, and switching patterns, among patients treated with selected systemic NSAIDs(including diclofenac)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M01AB05) diclofenac

diclofenac

(M01AC06) meloxicam

meloxicam

(M01AE01) ibuprofen

ibuprofen

(M01AE02) naproxen

naproxen

(M01AE03) ketoprofen

ketoprofen

(M01AH01) celecoxib

celecoxib

(M01AH05) etoricoxib

etoricoxib

Population studied

Short description of the study population

Adult patients receiving the prescription for the selected NSAIDS which includes dicofenac, meloxicam, ibuprofen, naproxen, ketoptofen, celecoxib and etoricoxib from October 1, 2012, to September 30, 2013, in the MarketScan databases and from April 1, 2013, to March 31, 2014, in the CPRD.

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

300000

Study design details

Outcomes

Patient characterization and prescription patterns

Data analysis plan

All study measures will be analyzed descriptively through the tabular and graphical display of mean values, medians, ranges, and standard deviations for continuous variables of interest and proportions for categorical variables (with corresponding 95% confidence intervals, as appropriate).

Documents

Study results

vol458a2001--legacy-clinical-study-report-redacted.pdf (6.37 MB)

Study report

vol458a2001-integrated-Final-Study-Report-abstract-redacted.pdf (136.14 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)

Clinical Practice Research Datalink

Data source(s), other

Truven Health Analytics' MarketScan Commercial Claims and Encounters Database (Commercial Database) United States, MarketScan Medicare Supplemental United States, Coordination of Benefits Database (Medicare Supplemental Database) United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown