A non-interventional, population-based register study on the prescription of etoricoxib (Arcoxia®) to dental surgery patients in the Nordic countries (MK-0663-170)

First published: 15/08/2014

Last updated: 11/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7134

Study ID

25929

DARWIN EU® study

No

Study countries

Denmark

Finland

Norway

Sweden

Study description

The objectives of this study are to:1) describe dispensed etoricoxib prescribed by dentists including the associated dental procedures, patient demographics, dosing, year, and country, 2) to described any dispensed etoricoxib prescribed by dentists that was not associated with dental procedures, 3) to describe off-label use of etoricoxib among patients aged less than 16 years and with doses >90 mg/day including the associated dental procedures, patient demographics, dosing, year, and country, 4) and to describe the duration of use of etoricoxib and the number of tablets dispensed.

Study status

Finalised

Research institutions and networks

Institutions

Department of Epidemiology, Institute of Applied Economics and Health Research (ApHER)

Denmark

First published: 22/02/2013

Last updated: 01/07/2019

Institution | Outdated | EU Institution/Body/Agency | ENCePP partner

Institute of Applied Economics and Health Research Copenhagen, Denmark, National Institute of Public Health, University of Southern Denmark Copenhagen, Denmark, School of Public Health, University of Tampere Tampere, Finland, Department of Health Management and Health Economics, University of Oslo Oslo, Norway, University of Gothenburg, Centre for Health Economics Gothenburg, Sweden

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.
ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Anders Green

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 25/04/2013

Study start date
Actual: 24/07/2014

Data analysis start date
Planned: 12/06/2017

Actual: 30/05/2017

Date of final study report
Planned: 27/11/2017

Actual: 27/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

0663-170-00_final-redaction.pdf (702.91 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary study objective is to characterize dispensed etoricoxib prescribed by dentists, including off-label use.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, population-based study of dispensed etoricoxib prescriptions in dental practice in the Nordic countries

Study drug and medical condition

Medicinal product name, other

Arcoxia

Medical condition to be studied

Dental care

Population studied

Short description of the study population

All individuals in the four Nordic countries in the period 2012-2013 with dispensed etoricoxib prescribed by dentists.

Age groups

- 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

1.000

Study design details

Outcomes

To describe: 1) dental prescriptions includeing the associated procedures, patient demographics, dosing, year, and country. 2) Use by dentists not associated with dental procedures. 3) Off-label use in patients <16 years of age and with doses >90 mg/day. 4) Duration of dental prescriptions and number of tablets dispensed. 5) Patients with concurrent prescriptions for anticoagulans.

Data analysis plan

Descriptive analyses: 1) Distribution of dental procedures in patients with etoricoxib prescribed by a dentist2) Distribution of the etoricoxib prescriptions overall and stratified by dose, patient demographics, year, and country. 3) Distribution of etoricoxib prescriptions, which are associated / not associated with one or more defined dental procedures 4) Distribution of off-label use (>90 mg, <16 years of age)5. Description of number of patients with concurrent prescriptions for anti-coagulants

Documents

Study results

p170mk0663-final-report_final-redaction.pdf (3.15 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), other

National Health Registries Denmark, National Health Registries Finland, National Health Registries Sweden, National Health Registries Norway

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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