Safety Data on Etoricoxib From Swedish Registries of Spondyloarthropathy/Ankylosing Spondylitis Patients (MK-0663-159; EP07013.013.11.082)

First published: 26/05/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19202

Study ID

27099

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

This study is a population- and register-based nationwide matched cohort study using data from 1987-2010, with updated linkage and repeat analysis planned for 2013-14. The study period will begin on 01-Jan-2001 and end on 31-Dec-2009 (or the latest date for which data are available from the various registers). This study is being conducted by Merck & Co. Inc. as a post-licensure commitment to the European Medicines Agency (EMA). The rationale for the study is to provide additional post-marketing safety data regarding the use of etoricoxib for the indication of ankylosing spondylitis.The specific project objectives are to: 1) Describe the characteristics of Swedish participants with inflammatory spondyloarthropathy / ankylosing spondylitis (SpA/AS), 2) Describe the use of etoricoxib and other cyclooxygenase-2 (COX-2 inhibitors)/non-selective nonsteroidal anti-inflammatory drugs (nsNSAIDs) in Swedish participants with SpA/AS, and 3) Estimate and compare the rates of clinical outcomes of special interest (gastrointestinal (GI), renovascular, cardiovascular (CV), and cerebrovascular) with use of etoricoxib and other COX-2 inhibitors/nsNSAIDs in Swedish patients with SpA/AS.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

datasharing@organon.com

Study contact

datasharing@organon.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/02/2011

Study start date

Actual: 15/02/2011

Data analysis start date

Planned: 30/11/2018

Actual: 06/12/2018

Date of interim report, if expected

Actual: 30/05/2013

Date of final study report
Planned: 14/12/2018

Actual: 06/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

MK-0663-159-00 Protocol Summary.pdf(2.05 MB)

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)

Other study registration identification numbers and links

NCT01327638

Methodological aspects

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Describe characteristics of Swedish participants with inflammatory SpA/AS, describe use of etoricoxib & other COX-2 inhibitors/nsNSAIDs in Swedish participants with SpA/AS, estimate & compare rates of clinical outcomes of special interest (GI, renovascular, CV, cerebrovascular) with use of etoricoxib & other COX-2 inhibitors/nsNSAIDs in Swedish participants with SpA/AS.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ETORICOXIB

Anatomical Therapeutic Chemical (ATC) code

(M01AH05) etoricoxib

etoricoxib

Medical condition to be studied

Ankylosing spondylitis

Spondyloarthropathy

Population studied

Short description of the study population

A patient was eligible for inclusion on the first date who have met all of the following criteria:

- Attended an out-patient clinic 2001-2010
- Age >=16 years on the date attended the out-patient clinic
- Registered with an ICD-code corresponding to SPA/AS (i.e. ICD10: M46.1, M46.8, M46.9, and ICD9: 720B, 720C or 720X for the appropriate periods) and AS (i.e. ICD10: M459 and ICD9: 720A for the appropriate periods)

Age groups

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)

Special population of interest

Other

Special population of interest, other

Ankylosing spondylitis and Spondyloarthropathy patients

Estimated number of subjects

21108

Study design details

Outcomes

Number of participants with characteristics of inflammatory SpA/AS, participants who used etoricoxib, participants who used other COX-2 inhibitors, participants who used nsNSAIDs, clinical outcomes of special interest. Outcomes included atherosclerotic CV events, atherosclerotic cerebrovascular events, congestive heart failure, severe hypertension, renovascular, and GI events.

Data analysis plan

Comparisons of clinical outcomes among the drugs of interest will be made by descriptive comparison of the point estimates for the incidence rates and their associated 95% confidence intervals (CIs), using both clinical and epidemiological judgment and in light of the limitations of this observational study. No formal statistical significance testing will be performed for purposes of such comparisons.

Documents

Study results

MK-0663-159 Interim Results Summary.pdf(3.36 MB)

p159mk0663-final-report_Final Redaction .pdf(3.65 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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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