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: 23/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/27099

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 institution and networks

Institutions

Merck & Co.
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Institution

Contact details

Study institution contact
Clinical Trials Disclosure Merck Sharp & Dohme Corp.
Study contact

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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 type

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 data collection

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 etoricoxi

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
100000096957
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

Data sources

Data source(s)
National Prescribed Drugs Register / Läkemedelsregistret

Data sources (types)
Administrative data (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