A Nested Case-control Post-authorization Safety Study of Etoricoxib and Other Non-steroidal Anti-inflammatory Therapies in a Cohort of Patients with Ankylosing Spondylitis (AS) in the UK, France and Germany (MK-0663-163)

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Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19094

Study ID

19095

DARWIN EU® study

No

Study countries

- France
- Germany
- United Kingdom

Study description

This study is a population-based cohort of patients with ankylosing spondylitis (AS) from general medical practices in the UK, France, and Germany with a nested case control component to assess associations between drug exposures of interest and clinical outcomes relevant to patients using cyclooxygenase-2 (COX-2) inhibitors / nonsteroidal anti-inflammatory drugs (NSAIDS).

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Institution | Pharmaceutical company

Contact details

Study institution contact

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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: 01/08/2009

Study start date

Actual: 17/08/2009

Data analysis start date

Actual: 01/07/2015

Date of final study report

Actual: 11/12/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

MK-0663-163-00 Protocol Summary.pdf(1.52 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

NCT01077843

Methodological aspects

Study type

Study type list

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

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe in European participants with AS: 1) use of etoricoxib 2) characteristics of those who use etoricoxib 3) to assess the safety profile of etoricoxib and other anti-inflammatory therapies with respect to specific clinical outcomes of interest (including upper GI, cardiovascular, cerebrovascular, and renovascular events) relative to non-use of these medications and relative to each other.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M01AH05) etoricoxib

etoricoxib

Medical condition to be studied

Ankylosing spondylitis

Population studied

Short description of the study population

Patients with ankylosing spondylitis (AS) from general medical practices in the UK, France, and Germany.

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)

Special population of interest

Other

Special population of interest, other

Ankylosing spondylitis patients

Estimated number of subjects

27381

Study design details

Outcomes

Outcomes included gastrointestinal events, ischemic/thrombotic cardiac, cerebrovascular, and peripheral vascular events, haemorrhagic cerebrovascular events, congestive heart failure, hypertension, acute renal impairment or failure, and sudden/ unexplained death.

Data analysis plan

Descriptive analyses of the AS cohort: A number of descriptive analyses will be done to characterize the patients who qualify for the AS cohort, their follow-up during the study period, their use of anti-inflammatory treatments during follow-up, and the crude incidence of the clinical outcomes of interest during follow-up.A nested case-control analysis will be performed on outcomes where at least 700 events are available for analysis. The case control analysis will estimate the odds of current exposure to etoricoxib and various other anti-inflammatory treatments, compared with non-exposure in European patients with AS.

Documents

Study results

MK-0663-163 Final Results Summary.pdf(3.66 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)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

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

Unknown