Etoricoxib in real-world clinical setting: it’s treatment outcome in patients with rheumatic diseases (RED)

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000317

Study ID

1000000317

DARWIN EU® study

No

Study countries

- ☐ Hungary
- ☐ Latvia

Study description

Rheumatic diseases (osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis) constitute of one of the most widespread, crippling and painful group of conditions. Osteoarthritis (OA) and rheumatoid arthritis (RA) are two of the most common rheumatic conditions, which account for a large percentage of disability and chronic pain in adults worldwide. It is known that knee osteoarthritis is the most common joint localization of OA, where OA is the most prevalent form of arthritis. One of the main and most disabling symptoms accompanying these conditions is pain. Nonsteroidal anti-inflammatory drugs (NSAIDs) represent the cornerstone of pain and inflammation therapy. Those medications often arise upper gastrointestinal problems, which might be the cause of discontinuation of therapy. Cyclooxygenase-2 selective inhibitors (COX-2), medicines used in pain and inflammation treatment, offer major advantage of reduced gastrointestinal toxicity, compared to non-selective NSAIDs. Etoricoxib, COX-2 selective inhibitor, has been well studied in patients with different rheumatic diseases, however mostly in randomized clinical trials, which may not accurately represent daily regular clinical practice characterized by heterogeneous population of patients. Non-interventional clinical study with Krka’s etoricoxib in real-world setting of heterogeneous population of rheumatic pain patients provides information about medicine performance in the real-world clinical practice and furthermore help us understand the role and value of Krka’s etoricoxib in improving patients’ outcomes. The study provides important therapeutic data, reflecting actual clinical aspects in the field of rheumatic diseases and pain management; additionally, the study evaluates the real-world effectiveness of Krka’s etoricoxib and consequently help investigators to take informed decisions on the treatment of patients with rheumatic diseases, especially osteoarthritis.

Study status

Finalised

Research institutions and networks

Institutions

Debreceni Egyetem ÁOK Reumatológiai Tanszék

Pauls Stradiņš Clinical University Hospital (Riga, Latvia)

Contact details

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Primary lead investigator

Zoltán Szekanecz

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2021

Actual: 26/07/2021

Study start date
Planned: 01/12/2021

Actual: 21/12/2021

Data analysis start date
Planned: 01/02/2023

Actual: 01/03/2023

Date of final study report
Planned: 02/10/2023

Actual: 26/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Representative offices or companies of Krka d.d., Novo mesto who participated in the study.

Study protocol

NIS_RED_protocol_summary_2024-06-10_clean.pdf(245.48 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

observational, prospective, non-interventional, international, multicentre

Main study objective:

Evaluate the real-world effectiveness of Krka’s etoricoxib, assessing pain intensity of rheumatic disease patients, investigate the advantages of a single-dose regimen, evaluate gastrointestinal tolerability and cardiovascular safety,

focusing also on patients with knee osteoarthritis.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is an international, non-interventional, observational, prospective, multicentre study evaluating the effectiveness of Krka’s etoricoxib in patients with rheumatic diseases (osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis) according to the investigator’s consideration and in compliance with SmPC of Krka’s etoricoxib. Only patients, who would have been otherwise also treated with Krka’s etoricoxib in local regular clinical practice, were enrolled in this international non-interventional study. Also, only patients who agreed with informed consent form and consent for statistical evaluation of personal data were included in the study. This protocol did not influence the decision of attending physician regarding patient management. Any diagnostic method or therapeutic decision made by a physician were independent from the inclusion of a patient in the study in accordance with its non-interventional design.

Study drug and medical condition

Name of medicine, other

Krka's etoricoxib

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

ETORICOXIB

Anatomical Therapeutic Chemical (ATC) code

(M01AH05) etoricoxib

etoricoxib

Medical condition to be studied

Pain

Osteoarthritis

Rheumatoid arthritis

Population studied

Short description of the study population

Patients with symptomatic rheumatic diseases (osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute gouty arthritis) who were indicated for treatment with etoricoxib and obtained Krka’s etoricoxib according SmPC and who agreed with informed consent form and consent for statistical evaluation of personal data, were included in the study.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Study design details

Outcomes

- Primary outcome:

o Assessing the mean absolute and relative reduction of pain intensity on VAS scale in patients with rheumatic diseases from 1st till 2nd data capture and separately for naïve and previously treated patients.

o Assessing proportion of patients with rheumatic diseases with clinically meaningful improvement of pain management (reduction of pain intensity is considered as clinically meaningful, if pain intensity does not exceed 30 mm on VAS or if the baseline intensity is reduced for at least 50%) at 2nd data capture and separately for naive and previously treated patients.

o Assessing the mean absolute improvement of five outcomes (pain, symptoms, function in daily living, sport and recreation function, knee-related quality of life) with KOOS questionnaire in patients with knee osteoarthritis from 1st till 2nd data capture and separately for naïve and previously treated patients.

- The secondary endpoints encompass 12 items realted with: previous teatments with rheumatic agents and/or analgesics, evaluation of reasons for discontinuing previous treatment with NSAIDs, evaluation of patient’s and investigator’s satisfaction with the Krka’s etoricoxib treatment, assessing cardiovascular safety of treatment with Krka's etoricoxib, satisfcation with Krka's etoricoxib dosign regimen, assessing proportion of patients with gastrointestinal problems, assessing proportion of patients who need in addition to Krka's etoricoxib treatment with other rheumatic agent/analgesic, assessing average time till the first follow-up, evaluating Krka's etoricoxib average dose and daily dose, assessing proportion of patients with comorbidities, evaluation of reasons for Krka's etoricoxib change at 2nd data capture, assessing the proportion of patient who experienced improvement in KOOS values, safety evaluation.

Data analysis plan

The study characteristics of the protocol were entered into electronic data capture system - the eCRF application. All data and clinical information were collected in accordance with the country specific privacy laws, Helsinki declaration, protocol and regular clinical practice. Corrections made in eCRF by the investigator were captured in audit trail log along. In case of missing, misleading or incomplete data during the study conductance, the monitor produced queries. Queries were forwarded to investigator's clarification. Only investigator or authorized study personnel could provide data change or data correction. The statistical report includes standard descriptive statistics. For numerical variables and each group in question, the largest and the smallest value in the associated sample, the sample mean and the sample standard deviation, were recorded. For categorical variables and each group in question, the numeri and percentages of the categories present are listed. All patients included in the study are also included in the safety analysis. Two-sided confidence intervals are computed individually at level of confidence 95 % (by inversion, this corresponds to hypothesis tests with simple null hypothesis, possibly with nuisance parameters, and two-sided alternatives at level of significance 5 %). In this study, only the full analysis set is considered.

Summary results

Part of separate document "Summary of results".

Documents

Study report

NIS_RED_summary_of_final report.pdf(846.58 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 sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

No

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes