Impact of naproxen sodium (Nalgesin® forte) treatment on the performance of daily activities in patients with low back pain or osteoarthritis in regular clinical practice (QLIFE)

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000831

Study ID

1000000831

DARWIN EU® study

No

Study countries

Bosnia and Herzegovina

Kazakhstan

Mongolia

North Macedonia

Serbia

Slovenia

Study description

Low back pain is a common global health issue, limiting activity and causing work absence. Treatment guidelines recommend patient education, reassurance, early return to normal activities, and non-steroidal anti-inflammatory drugs as first-line medication. The goal is to improve function and quality of life. Osteoarthritis is a major cause of disability in older adults, affecting the entire joint and leading to pain, stiffness, and reduced mobility. Oral NSAIDs are the main pharmacologic treatment for knee, hip, and hand osteoarthritis. While many therapies aim to relieve symptoms, none prevent or reverse the disease or offer long-term relief. Naproxen sodium is the sodium salt of naproxen, with analgesic, anti-inflammatory, and antipyretic effects. It is widely used for rheumatic conditions (e.g., rheumatoid arthritis, osteoarthritis), acute injuries, and various pain types. Non-interventional study with Krka’s naproxen sodium 550 mg in real-world setting of heterogenous population of patients with low back pain or osteoarthritis assesses and explores effect of treatment with Krka’s naproxen sodium on pain, mobility and function of patients with low back pain or osteoarthritis in regular clinical practice. The study provides information on correlation between pain control and patient’s ability to perform different activities of daily living, which will be further communicated to health care professionals.

Study status

Finalised

Research institutions and networks

Institutions

Primary Healthcare of Gorenjska, Škofja Loka Health Centre, Stara cesta 10, 4220 Škofja Loka, Slovenia

Clinical Center of Serbia, Clinic for Physical Medicine and Rehabilitation, Pasterova 2, 11000 Belgrade, Serbia
Clinical Hospital Acibadem Sisitina, Skupi 5A, Skopje 1000 North Macedonia
Health Centre "Sveti Vračevi" Čelinac, Vidovdanska 5, Čelinac, Bosnia and Herzegovina
Republican Public Association Qazaq College of Rheumatology, 210B Dostyk Avenue, Almaty 050010, Republic of Kazakhstan
Mongolian National University of Medical Science, Amgalan Botanical Garden, BZD 12 khoroo, Ulaanbaatar 13270

Contact details

Study institution contact

Maruša Ostanek marusa.ostanek@krka.biz

Study contact

marusa.ostanek@krka.biz

Primary lead investigator

Aleksander Stepanović

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2022

Actual: 08/11/2022

Study start date

Planned: 01/04/2023

Actual: 12/06/2023

Data analysis start date

Planned: 04/11/2024

Actual: 21/11/2024

Date of final study report

Planned: 30/06/2025

Actual: 23/05/2025

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_QLIFE_protocol_summary_2025-07-24.pdf (244.7 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

Other

If ‘other’, further details on the scope of the study

Patient reported outcomes

Data collection methods:

Primary data collection

Study design:

observational, prospective, non-interventional, international, multicentre

Main study objective:

Provide data about the effectiveness of Krka’s naproxen sodium in reducing pain in correlation with improving ability to perform daily living activities in patients with low back pain or osteoarthritis in regular clinical practice and to provide the frequency of adverse events during observation.

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 naproxen sodium 550

mg in patients with low back pain or osteoarthritis according to the investigator’s consideration and in compliance with SmPC of Krka’s naproxen sodium. Only patients, who would have been otherwise also treated with Krka’s naproxen sodium 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

Medicinal product name

NAPROXEN

Medicinal product name, other

Krka’s naproxen sodium

Anatomical Therapeutic Chemical (ATC) code

(M01AE02) naproxen

naproxen

Medical condition to be studied

Pain

Population studied

Short description of the study population

Patients with low back pain or osteoarthritis and with average pain intensity in last 24 hours of ≥ 3 on numeric rating scale who were indicated for treatment with Krka’s naproxen sodium 550 mg according to 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)
    - Adults (85 years and over)

Study design details

Outcomes

Primary outcome: Proportion of patients with improved ability to perform overall activities of daily living after an up to 4-week treatment with Krka’s naproxen sodium 550 mg as described in this protocol for all patients.
Secondary outcomes: The secondary endpoints encompass 15 items related to proportions of patients with improved ability to perform activities of daily living, separately for mobility, daily routine, socializing, general well-being/mood swings; absolute and relative changes of current pain intensity, average pain intensity and worst pain intensity in the last 24h, comparison of absolute and relative mean changes of all three pain intensities among patients, treated with

a 2-times-daily dosing regimen vs. other dosing regimen and patients adhering to prescribed therapy with Krka’s naproxen sodium 550 mg vs. patients not adhering to prescribed therapy with Krka’s naproxen sodium 550 mg; evaluation of prescription practices of general practitioners vs. specialist; evaluation of additional prescription for managing of pain; assessment of patient’s satisfaction with the treatment in general and separately with twice daily dosing regimen; assessment of patient’s condition improvement; comparison of incidence of gastrointestinal adverse events between patients with and without prescription of gastro-protective agents and evaluation of tolerability of treatment with Krka’s naproxen sodium 550 mg.
Additionally primary endpoint and selected secondary endpoints will be evaluated also separately for group of patients only with LBP and group of patients only with OA.

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. In case of missing, misleading or incomplete data during the study conductance, the monitor raised queries. These queries were forwarded to the investigator for clarification. Only the investigator or authorized study personnel were permitted to make data changes or corrections. Summary statistics consist of the number of patients/observations, frequencies and corresponding percentages for categorical variables, and of the number of patients/observations, mean, median, standard deviation, minimum and maximum, first and third quartile for numeric variables. Some variables (numeric discrete variables with few possible values) were summarized both as categorical variables and as numeric

variables. Each endpoint was assessed by reporting the appropriate summary statistics and some also by appropriate methods of inferential statistics. All statistical tests are conducted with a significance level (alpha) of 5%, corresponding to a Type I error rate of 0.05. All patients included in the study are also included in the safety analysis.

Summary results

Part of separate document “Summary of results”.

Documents

Study report

NIS_Qlife_summary_final_report_0511202.pdf (305.38 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