Real world management of pain: Do patient-specific factors influence treatment decisions and its outcomes? (RELIEF)

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000079

Study ID

1000000079

DARWIN EU® study

No

Study countries

- [ ] Bosnia and Herzegovina
- [ ] Croatia
- [ ] Czechia
- [ ] North Macedonia

Serbia

Study description

Pain of any type is the most common reason to consult the doctor and is one of the leading domains of disability worldwide. It is estimated that 40–60% of patients with chronic pain have inadequate management of their pain, while also management of acute pain remains inadequate across various treatment settings. Thus, epidemiological study RELIEF explored if and how patient-specific factors play a role in the selection of medications for pain management, especially NSAIDs and paracetamol/tramadol combination, in five European countries. As quality of life is increasingly being recognized as one of the most important parameters to be measured in the evaluation of pain management therapies, the study has additionally observed influence of pain and corresponding treatment choices on patient's quality of life in usual care settings. Obtained findings have been transferred to professional public in order to improve pain management of any type and duration in daily practice.

Study status

Finalised

Research institutions and networks

Institutions

University Clinic for Traumatology, Orthopaedic Diseases, Anaesthesia, Reanimation, Intensive Care and Emergency Center, Skopje, North

Macedonia

Privatna ortopedska ordinacija “Prof.dr. Mirza Biščević“, Sarajevo; Bosnia and Herzegovina; Klinički centar Vojvodine, Novi Sad, Serbia; Centrum pro léčení a výzkum bolestivých stavů při Klinice rehabilitace a tělovýchovného lékařství, Fakultní nemocnice v Motole, Prague, Czecha; Klinički bolnički centar Zagreb, Zagreb, Croatia; University Clinic for Traumatology, Orthopaedic Diseases, Anaesthesia, Reanimation, Intensive Care and Emergency Center, Skopje, North Macedonia.

Contact details

Study institution contact

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Primary lead investigator

Antonio Gavrilovski

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2020

Actual: 07/07/2020

Study start date

Planned: 01/12/2020

Actual: 10/12/2020

Data analysis start date

Planned: 01/02/2022

Actual: 08/03/2022

Date of final study report

Planned: 30/09/2022

Actual: 14/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Representative offices or companies of Krka d.d., Novo mesto in Bosnia and Herzegovina, Croatia, Czech Republic, North Macedonia and Serbia.

Study protocol

05_EpiS_RELIEF_protocol_clean_ver.1.0-2020-07-30_summary_2023-11-28.pdf
(291.97 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

KEPSU13/2020–RELIEF

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Study design:

Observational, prospective, non-interventional, international, multicentre, epidemiological study.

Main study objective:

The main study objective is to find out if and how patient-specific risk, intensity, type and duration of pain determine the choice of analgesic treatment (NSAIDs and/or tramadol/paracetamol combination), and evaluate the influence of pain and corresponding treatment choices on quality of life.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is observational, prospective, non-interventional, international, multicentre, epidemiological study. In this epidemiological study were included only patients, who would also otherwise be treated in usual clinical practice with NSAIDs and/or tramadol/paracetamol combination and who agreed with the informed consent form and consent in collection, analysis and processing of

personal data, which were collected during the epidemiological 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 epidemiological design.

Study drug and medical condition

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

DICLOFENAC

ETORICOXIB

IBUPROFEN

Anatomical Therapeutic Chemical (ATC) code

(M01AB05) diclofenac

diclofenac

(M01AE01) ibuprofen

ibuprofen

(M01AH05) etoricoxib

etoricoxib

(M02AA12) naproxen

naproxen

(N02AJ13) tramadol and paracetamol

tramadol and paracetamol

(N02AX02) tramadol

tramadol

(N02BE01) paracetamol

paracetamol

Medical condition to be studied

Back pain

Headache

Additional medical condition(s)

Neuropathic pain, other musculo-skeletal pain, trauma/injury pain (including postoperative pain), rheumatic pain and other types of pain

Population studied

Short description of the study population

Patient with pain (regardless of the type, level of intensity and duration) who need treatment with NSAIDs and/or tramadol/paracetamol combination, alone or in combination with other analgesics 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)

Estimated number of subjects

4496

Study design details

Outcomes

Primary outcome: To evaluate how average intensity of pain in last 24 hours on VAS scale influences the prescription of analgesics (NSAIDs and/or tramadol/paracetamol combination) and to compare these influences among physicians in participating countries. To evaluate how patient's risk factors influence the prescription of analgesics and to compare these variations among participating countries.

The secondary endpoints encompass 11 items realted with: demographic, risk factors, concomitant diseases, duration of pain, type of pain, quality of life, pain intensity, adherence, patient's and investigator's satisfaction with the treatment, investigator's specialties, 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 were captured in audit trail log along with the date, person credentials and reason of correction. 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 locked database was used for the final statistical analysis and final study report. 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.

Documents

Study report

06_EU_PAS_Register_summary_of_final_report_with_sig_page.pdf(730 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