Evaluation of the Use of Nepafenac in Selected European Populations

First published: 27/11/2013

Last updated: 13/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20038

EU PAS number

EUPAS5278

Study ID

20038

DARWIN EU® study

No

Study countries

☐ Denmark

☐ Netherlands

Study description

This study is a drug utilization study to evaluate the use of nepafenac (Nevanac), an ophthalmic non-steroidal agent, in two selected European populations from Denmark and The Netherlands. In Europe, nepafenac has been approved for (1) prevention and treatment of postoperative pain and inflammation associated with cataract surgery in adults (approval in 2007) and (2) to reduce the risk of macular edema after cataract surgery in diabetic patients (approval in 2011). The aim of this study is describe the use of nepafenac.This will be a cohort study including new users of nepafenac and new users of other selected ophthalmic NSAIDs. The study will be conducted in the network of databases from the National Health Databases in Denmark and the PHARMO Record Linkage System database in the Netherlands. Patients will become eligible for cohort entry after 6 months of enrolment in the databases.The exposure will be based on dispensed prescriptions, medical condition concomitant to the exposure will be derived from diagnoses and procedures around the prescription dispensing date. Target conditions for this evaluation are cataract surgery, refractive procedures, other ophthalmic procedures, two or more ophthalmic surgeries or procedures, dry eye/Sjögren syndrome, uveitis/iritis, ophthalmic manifestations of allergy, ocular pain, macular edema, vitreous-related disorders.The study will report the frequency of the demographic characteristics of nepafenac users and users of other selected individual ophthalmic NSAIDs. The potential off-label use of nepafenac will be characterized as, a) use not preceded by cataract surgery b) use preceded by cataract but longer than 21 days in patients without diabetes or longer than 60 days in patients with diabetes c) use in individuals aged less than 19 years.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

N/A

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

- [ ] Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom
- ☐ United Kingdom (Northern Ireland)
- ☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Pharmacoepi center, University of Southern Denmark

- ☐ Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Alejandro Arana Navarro

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2013

Actual: 25/03/2013

Study start date

Planned: 30/06/2015

Actual: 22/09/2015

Data analysis start date

Planned: 01/08/2015

Actual: 22/09/2015

Date of final study report

Planned: 31/03/2016

Actual: 31/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alcon Labs, Inc.

Study protocol

Redacted Nevanac Protocol Summary.pdf(584.01 KB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to characterize off-label use of nepafenac.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(S01BC10) nepafenac

nepafenac

Medical condition to be studied

Off label use

Population studied

Short description of the study population

New users of nepafenac and new users of other selected ophthalmic NSAIDs with at least 6 months of previous enrolment in the database.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

Estimated number of subjects

4000

Study design details

Data analysis plan

The analysis will be descriptive. In the baseline analysis, characteristics of users of nepafenac and users of other selected ophthalmic NSAIDs will be assessed at the cohort entry date. The medical condition associated with use of nepafenac and other ophthalmic NSAIDs will be also assessed.In the treatment period analysis, a) patterns of duration of prescriptions for nepafenac or other ophthalmic NSAIDS will be evaluated, especially those of off-label duration b) patterns of duration of prescriptions for nepafenac or other ophthalmic NSAIDs without prior cataract surgery will be evaluated c) the proportion of patients using specific medications during treatment with nepafenac or other ophthalmic NSAIDs will be evaluated.

Documents

Study publications

Margulis AV, Houben E, Hallas J, Overbeek JA, PottegAard A, Torp-Pedersen T, Pe...

Data management

Data sources

Data source(s)

Odense Pharmacoepidemiological Database

PHARMO Data Network

Data sources (types)

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

No