Localised Neuropathic Pain (LNP) managed in the primary care setting in France, Ireland, Italy, Spain, and the United Kingdom: A cross-sectional study of prevalence, clinical characteristics, treatment patterns and patient's reported outcomes

First published: 21/09/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/25369

EU PAS number

EUPAS15418

Study ID

25369

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Ireland
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

Topical application of analgesics can offer a valid therapeutic alternative, providing Localised Neuropathic Pain (LNP) is recognised. To date only sparse data are available in literature about the features of LNP, its therapeutic management and its frequency in the primary care population in Europe. This study will attempt to fill such a knowledge gap in the primary care population of five EU countries, namely France, Ireland, Italy, Spain and the United Kingdom. Data on the frequency of LNP and the clinical profile of patients showing signs and symptoms of LNP, their current treatment patterns, and patient's reported health status, including quality of sleep, can help to identify unmet medical needs in such a problematic therapeutic area.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

National Institue for Health Research (UK),Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Actual: 01/04/2016

Study start date
Planned: 01/10/2016

Actual: 13/12/2016

Date of final study report
Actual: 04/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Grunenthal GmbH

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:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To describe treatment characteristics and patterns of treatment of LNP patients identified among chronic pain patients in primary care in 5 EU countries.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Pain management

Population studied

Short description of the study population

Patients showing signs and symptoms of localised neuropathic pain (LNP) in the primary care setting in France, Ireland, Italy, Spain, and the United Kingdom.

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)

Estimated number of subjects

1000

Study design details

Outcomes

The primary endpoints for the study will be the important clinical and treatment characteristics at the time of the visit, including but not limited to: clinical characteristics, aetiology of LNP, co-morbidities and therapy for chronic pain in the 6 moths preceding the screening, current analgesia for chronic pain, - EQ-5D score (Patient’s self-reported health status) - CPSI scores (Patient’s self-reported quality of sleep) - Prevalence of LNP

Data analysis plan

Analyses will be mainly descriptive in nature. Categorical data will be summarized by counts and percentages. Continuous data will be summarized using number, mean, standard deviation (SD), median, quartiles, minimum and maximum and in the case of non-normally distributed data, median, range and interquartile range. All statistical tests used for comparisons to assess

differences or associations will be 2-sided and conducted at the 0.05 alpha level. P-values will be presented to three decimal places.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional patient based data collection

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