

Insights into real-world treatment of cluster headache through a large Italian database: prevalence, prescription patterns, and costs

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000262>

EU PAS number

EUPAS1000000262

Study ID

1000000262

DARWIN EU® study

No

Study countries

Italy

Study description

Objective: This study aimed at estimating the treated cluster headache (CH) prevalence and describing prescription patterns and direct costs paid by the Italian National-Health-System.

Methods: Through the ReS database (healthcare administrative data collection of a large sample of the Italian population), adults in treatment for CH (acute therapy with sumatriptan/subcutaneous or oxygen, associated with preventive therapy with verapamil or

lithium) were selected. A cross-sectional analysis described the prevalence of CH-treated subjects repeated annually in 2013–2017. A longitudinal analysis of patients selected in 2013–2015 and followed for 2 years provided the prescription patterns.

Results: The annual prevalence of CH-treated patients increased from 6.4×100,000 adults in 2013 to 6.7 in 2017. In 2013–2015, 570 patients (80.7% M; mean age 46) treated for CH were found. In 50.4%, the identifying CH treatment was sumatriptan/subcutaneous+verapamil. During follow-up, >1/3 changed the preventive drug and interruption was the most frequent modification, although acute treatments were still prescribed. The mean annual cost/patient ranged from €2,956 to €2,267; pharmaceuticals expenditure represented the 56.4% and 57.3%, respectively.

Conclusions: This study showed an important unmet need among CH patients, carrying a high economic burden that should be considered in the evaluation of the impact of incoming therapies (e.g. Calcitonin-Gene-Related-Peptide antibodies).

Study status

Finalised

Research institution and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

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12/04/2024

Institution

ENCePP partner

Not-for-profit

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:

12/06/2019

Study start date

Actual:

12/07/2019

Date of final study report

Actual:

11/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Healthcare resource utilisation

Data collection methods:

Secondary data collection

Study design:

Retrospective longitudinal cross sectional cohort study.

Main study objective:

This study aimed at estimating the treated cluster headache (CH) prevalence and describing prescription patterns and direct costs paid by the Italian National-Health-System.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Cluster headache

Population studied

Short description of the study population

Adult patients affected by Cluster headache and treated with specific drugs for acute attack associated with a preventive therapy were selected.

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

Setting

In-hospital and local outpatient settings in public and affiliated with SSN facilities.

Summary results

The annual prevalence of CH-treated patients increased from 6.4×100,000 adults in 2013 to 6.7 in 2017. In 2013–2015, 570 patients (80.7% M; mean age 46) treated for CH were found. In 50.4%, the identifying CH treatment was sumatriptan/subcutaneous+verapamil. During follow-up, >1/3 changed the preventive drug and interruption was the most frequent modification, although acute treatments were still prescribed. The mean annual cost/patient ranged from €2,956 to €2,267; pharmaceuticals expenditure represented the 56.4% and 57.3%, respectively.

Documents

Study publications

[Insights into real-world treatment of cluster headache through a large Italian ...](#)

Data management

Data sources

Data source(s)

Database of Fondazione ReS

Data sources (types)

[Administrative data \(e.g. claims\)](#)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes