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

**First published:** 15/07/2024

**Last updated:** 15/07/2024

Study Finalised

## Administrative details

**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 crosssectional 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).

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**Study status**

Finalised

## Research institutions and networks

## Institutions

### Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

**First published:** 05/07/2017

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Institution | Not-for-profit | ENCePP partner

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Letizia Dondi

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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**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.

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**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.

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**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

## 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 source(s)**

Database of Fondazione ReS

**Data sources (types)**

Administrative healthcare records (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