

Primary Sjögren's syndrome in Italy: real-world evidence of a rare disease through administrative healthcare data

First published: 12/04/2024

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Study

Finalised

Administrative details

EU PAS number

EUPAS1000000110

Study ID

1000000110

DARWIN EU® study

No

Study countries

 Italy

Study description

Objectives

Primary Sjögren's syndrome (pSS) is a systemic autoimmune disease with significant impact on morbidity, mortality, and quality of life. This study aimed to evaluate epidemiology, healthcare needs and related costs of pSS patients, from the Italian National Health Service (INHS) perspective.

Methods

From the Fondazione Ricerca e Salute's database (~5 million inhabitants/year), pSS prevalence in 2018 was calculated. Demographics, mean healthcare consumptions and direct costs at one year following index date (first in-hospital diagnosis/disease waiver claim) were analysed through an individual direct matched pair case-control analysis (age, sex, residency).

Conclusion

According to the results of this population-based study, the prevalence of pSS in Italy appears to be consistent with the definition of rare disease. Patients with pSS have higher pharmacological, in-hospital and outpatient specialist care needs, leading to three-times higher overall cost for the INHS, compared to the general population.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner



Italy

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Institution

Not-for-profit

ENCePP partner

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/07/2023

Study start date

Actual: 04/07/2023

Date of final study report

Actual: 04/09/2023

Sources of funding

- Non-for-profit organisation (e.g. charity)

More details on funding

This study was unconditionally supported by the Italian Association of people with Sjögren's syndrome (A.N.I.Ma.S.S. ODV - Associazione Nazionale Italiana Malati Sindrome Sjögren).

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

Study design:

Individual direct matched pair case-control analysis (age, sex, residency).

Main study objective:

This study aimed to evaluate epidemiology, healthcare needs and related costs of patients with primary Sjogren Syndrome, from the Italian National Healthcare Service perspective.

Population studied

Short description of the study population

People with primary Sjogren Syndrome cared by the Italian National Healthcare Service

Study design details

Setting

Inpatient and outpatient

Summary results

In Italy, 3.8/10,000 inhabitants were identified as affected by pSS (1,746 case: 1,746 controls) in 2018. In the year following index date, 53.7% of cases and 42.7% of controls received ≥ 1 drug ($p < 0.001$); mean per capita cost was €501 and €161, respectively ($p < 0.01$). At least one hospitalization occurred to 7.8% of cases and 3.9% of controls ($p < 0.001$) with mean per capita costs of €416 and €129, respectively ($p = 0.46$). At least one outpatient specialist service was performed in 49.8% of cases and 30.6% of controls ($p < 0.001$); mean per capita costs were €200 and €75, respectively ($p < 0.01$). Overall, mean annual costs were €1,171 per case and €372 per control ($p < 0.01$).

Documents

Study publications

<https://www.sciencedirect.com/science/article/pii/S0953620524000645>

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), other

Italian administrative healthcare database

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

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Yes