# Primary Sjögren's syndrome in Italy: realworld evidence of a rare disease through administrative healthcare data

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## 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

#### **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: 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  $\geq 1$  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**

## 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

Yes		
Check completeness		
Yes		

Check stability

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

Yes