A retrospective observational study on characteristics, treatment patterns, and healthcare resource use of patients with xerostomia in primary care settings using Optimum Patient Care Research Database in United Kingdom.

First published: 23/11/2021 Last updated: 23/04/2024





## Administrative details

#### **EU PAS number**

**EUPAS44384** 

Study ID

48502

**DARWIN EU® study** 

No

**Study countries** 

☐ United	Kingdom
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### **Study description**

The general aim of the study is to gain a better understanding of the xerostomia patients, in terms of their characteristics, treatment patterns, and burden in primary care including primary healthcare resource use and associated costs. The objectives of the study are: Primary objective • To describe patients newly diagnosed with xerostomia in terms of their sociodemographic characteristics, comorbidities, and treatments susceptible to cause xerostomia prior to index date. Secondary objectives • To describe treatment for xerostomia and associated costs, post-index date. • To describe primary healthcare resource use and associated costs, pre- and post-index date in patients with xerostomia.

#### **Study status**

**Finalised** 

## Research institutions and networks

## **Institutions**

## **OPEN Health**

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

### Contact details

### **Study institution contact**

Hosnijeh Fatemeh Saberi fatemehsaberihosnijeh@openhealthgroup.com

Study contact

fatemehsaberihosnijeh@openhealthgroup.com

### **Primary lead investigator**

Price David

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Actual: 12/10/2021

### Study start date

Planned: 29/07/2022

Actual: 01/08/2022

### **Data analysis start date**

Planned: 29/07/2022

Actual: 08/08/2022

### **Date of final study report**

Planned: 30/09/2022

Actual: 08/11/2022

## Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Colgate Palmolive

## Study protocol

Colgate\_Xerostomia\_Protocol\_COGA2002\_V1.1\_22.11.21 FINAL.pdf (1.12 MB)

# 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

#### **Data collection methods:**

Secondary use of data

### Main study objective:

The general aim of the study is to gain a better understanding of the xerostomia patients, in terms of their characteristics, treatment patterns, and burden in primary care including primary healthcare resource use and associated costs.

## Study Design

### Non-interventional study design

Cohort

Other

### Non-interventional study design, other

Retrospective observational study

# Study drug and medical condition

#### Medical condition to be studied

Dry mouth

# Population studied

### Short description of the study population

Patients with xerostomia aged 18 years or older identified from the Optimum Patient Care Research Database (OPCRD).

#### Inclusion criteria:

1. Patients with a first record of a diagnosis of xerostomia or dry mouth during the study eligibility period (see Table 1 for code list)

#### Exclusion criteria:

- 1. Patients with <12 months baseline data prior to index date
- 2. Patients with <12 months follow-up data post index date
- 3. Patients <16 years old

#### Age groups

- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

### Special population of interest

Other

### Special population of interest, other

Patients with xerostomia

### **Estimated number of subjects**

12625

## Study design details

#### **Outcomes**

To describe patients newly diagnosed with xerostomia in terms of their sociodemographic characteristics, comorbidities, and treatments susceptible to cause xerostomia prior to index date. To describe treatment for xerostomia and associated costs, post-index date. To describe primary healthcare resource use and associated costs, pre- and post-index date in patients with xerostomia.

#### Data analysis plan

All statistical analyses will be documented in a formal statistical analysis plan (SAP) that will be finalised prior to database lock. All analyses will be descriptive. Distributions and descriptive statistics of central tendency (medians and arithmetic means) and dispersion (standard deviation, interquartile range, and range) will be presented for quantitative variables wherever possible. Categorical variables will be described with frequencies and percentages. No statistical comparisons will be performed between groups. As patients' follow-up will likely differ between patients, healthcare resource use and cost will be expressed per person-years, using all person-years at risk for each patient. Costs for primary care activity and delivery of treatment will be derived from the BNF Drug Costs for cost treatment, and National Health Service (NHS) reference costs in Personal Social Services Research Unit (PSSRU) for activity (23–25).

## 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)

Optimum Patient Care Research Database

### **Data sources (types)**

Electronic healthcare records (EHR)

## 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**

# Data characterisation

### **Data characterisation conducted**

No