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

Study Finalised

Administrative details

EU PAS number

EUPAS44384

Study ID

48502

DARWIN EU® study

No

Study countries

United Kingdom

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 socio-demographic 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

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Institution

Contact details

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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)
- Adults (46 to < 65 years)
- 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 socio-demographic 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

Unknown

Data characterisation

Data characterisation conducted

No