Incidence, prevalence and burden of Dry Eye diseAse in France (IDEA)

First published: 03/05/2019

Last updated: 24/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS29618

Study ID

49825

DARWIN EU® study

No

Study countries

France

Study description

Dry Eye Disease (DED) is a multifactorial disorder due to excessive tear evaporation and/or insufficient tear production. The multiplicity of criteria (signs, symptoms, feelings) potentially used to define DED makes the

assessment of DED prevalence complex (5 to 50% according to the Dry Eye Workshop II (DEWS II) of the Tear Film and Ocular Surface (TFOS) Society). Treatment of DED mainly relies on artificial tears and lifestyle advice for mild and medium stage. In some severe cases pharmacological therapy such as cyclosporine or lacrimal punctual plugs can be necessary. In France, most of the tears substitutes are reimbursed (11.3 millions of packs in 2015). All healthcare consumption regardless physician specialities would be very helpful to fully assess DED burden in France. In the context of the European Marketing Authorization Application for a new treatment for DED, Shire wants to better understand the burden of DED, through healthcare consumption regardless physician. This project is designed to estimate the prevalence and the incidence of the disease in France, as well as assess baseline characteristics of patients, treatment pattern, disease evolution, healthcare resource use and costs using EGB, a 1/97 permanent representative sample of the French nationwide claims database (SNDS). Patients with at least 3 dispensing of artificial tears over a 6-month period or one dispensing of ocular cyclosporine in 2014-2015 will be included and followed for 2 years. The French health technology assessment agency (Haute Autorité de Santé - HAS) estimates the population with DED between 3.5 and 4.7 millions of subjects in France, including 1 million with moderate or severe disease, that represents approximately 10 000 subjects expected in this EGB study. The study was cancelled at the request of the sponsor, SHIRE. The drug of interest was transferred to another pharmaceutical company which decided not to continue the associated study. Study final date: 2019/10/21

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Patrick Blin plateforme.bpe@u-bordeaux.fr

Study contact

plateforme.bpe@u-bordeaux.fr

Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/05/2018

Study start date
Planned: 30/05/2019

Actual: 21/10/2019

Data analysis start date
Planned: 30/05/2019

Date of final study report
Planned: 30/09/2019

Actual: 21/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Shire

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

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective is to estimate the DED prevalence and incidence in France in 2014 and 2015.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dry eye

Population studied

Short description of the study population

Subjects with dry eye disease (DED) identified from the French nationwide claims database (SNDS).

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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 dry eye disease

Estimated number of subjects

10.000

Study design details

Data analysis plan

The following analyses will be performed:- A flow chart and an attrition table depicting the number of patients identified in the database- Description of

patient baseline demographics and clinical characteristics, according to prevalent/incident status and DED severity level- Estimation of the annual prevalence and incidence of DED in 2014 and 2015 in the French population. Prevalence by DED severity level will also be computed- Description of treatment pattern at the index date (stratified on incident/prevalent status and DED severity level), and during the follow-up period (stratified on DED severity only)- Description of the disease evolution (switch between DED severity levels over the follow-up period and duration of severity stages)- Description of healthcare resource use and costs for one and two years from the National Health Insurance perspective and for the collective perspective stratified by DED severity level

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 sources (types)

Administrative healthcare records (e.g., claims)

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