Nation-wide health resource consumption and costs associated with mepolizumab (Nucala): a French SNDS database study (Resala)

First published: 06/01/2021

Last updated: 14/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS38868

Study ID

38869

DARWIN EU® study

No

Study countries

France

Study description

Currently, no study has addressed real-life data describing changes in health resource consumption and related costs attributable to mepolizumab treatment. The aim of the current study is to fill this knowledge gap by performing an exhaustive extraction of data for patients receiving mepolizumab in the French single-payer health care system. The change in real-life health-resource usage and costs observed for these patients would provide the first evidence that mepolizumab is changing the care landscape for eligible severe asthma patients. The overall objectives of this study are: (i) using the SNDS French national database, to identify a representative, nation-wide population of patients treated with mepolizumab with a follow-up period of at least 12 months, (ii) to describe the initial one-year changes in health resource use before and after the initiation of mepolizumab treatment and (iii) to estimate the change in associated costs for the first year of treatment. These initial data will additionally serve as a basis for the design of longer-term studies.

Study status

Planned

Research institutions and networks

Institutions

Plateforme A3TOS

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicolas Molinari

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/08/2020

Actual: 31/08/2020

Study start date

Planned: 01/02/2021

Data analysis start date

Planned: 01/02/2021

Date of final study report

Planned: 30/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

Resala_protocol_2020-05-14_for_public_release.pdf (478.12 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

https://osf.io/zg3us/,,NCT04550780

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

(i) using the SNDS French national database, to identify a representative, nation-wide population of patients treated with mepolizumab with a follow-up period of at least 12 months, (ii) to describe the initial one-year changes in health resource use before and after the initiation of mepolizumab treatment and (iii) to estimate the change in associated costs for the first year of treatment.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

MEPOLIZUMAB

Medical condition to be studied

Asthma

Additional medical condition(s)

We will be extracting data for all persons prescribed Mepolizumab.

Population studied

Age groups

- 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)

Estimated number of subjects

2.813

Study design details

Outcomes

• To estimate the change in associated costs for the first year of treatment Total health care costs for the year preceding the initiation of mepolizumab, as well as for the year after. • To describe the initial one-year changes in health resource use before and after the initiation of mepolizumab treatment Cumulative estimates for health resource use and associated costs for the year preceding the initiation of mepolizumab, as well as for the year after. • To further characterize rates of change in health resource usage and/or costs in subpopulations of interest

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Data analysis plan

Differences between the two study periods will be presented with their 95% confidence intervals, as well as significance testing for paired data. Changes in total costs with time will also be visually presented using mean cumulative function step curves. The cost rate curve (ie the slope of the mean cumulative cost curve) will be determined by a 28-day sliding window for the

demonstration of changes in the speed of accumulating costs. Mean cumulative functions describing the difference between baseline and exposure periods can be computed. For the latter, the elapsed time at which the 95% confidence interval no longer contains zero indicates differences in cumulative costs. Similarly, mean cumulative functions for events of interest (specific health resource usages or associated costs found to differ before versus after T0) can be computed.

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