REACH study: Real-World Evidence study of OM-85 in Adults and Children in China, Italy, and Belgium

First published: 06/12/2024

Last updated: 27/06/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000316

Study ID

1000000316

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ China
- ☐ Italy

Study description

This non-interventional study is designed to investigate the effectiveness of OM-85 in the prevention of Respiratory Tract Infection (RTI) episodes and to understand the management of patients with RTI. The objectives will be studied separately in Belgium, Italy and China and will include description and comparison of RTI episodes before and after initiating OM-85 treatment, comparison of RTI episodes in patients initiating OM-85 treatment and in a non-user group, pattern of prescription of OM-85, antibiotics and other concomitant medications of interest, and healthcare resource utilisation.

As primary objectives, the effectiveness of OM-85 is assessed through (1) a before-after design, comparing the rate of RTI episodes before and after initiation of OM-85, and (2) a comparative effectiveness design, comparing the rate of RTI episodes during follow-up between patients who initiated OM-85 and patients who did not initiate OM-85.

The Target Trial Emulation is used as the framework for the design of this non-interventional study.
The study period will start from the date of earliest data availability and end at the date of latest data availability in each of the data sources. The study period will include an inclusion period, a baseline period, an initiation grace period and a follow-up period. The outcomes will be assessed at 3, 6, 9, 12, and 24 months after the initiation grace period, as per data availability.

The overall study population will include patients aged ≥ 1 year of age with ≥1 RTI episodes and no prescriptions of bacterial lysates within 12 months prior to the inclusion (baseline period).

Study status

Planned

Research institutions and networks

Institutions

Parexel International

United States

First published: 19/10/2010

Last updated: 10/12/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Katja Hakkarainen katja.hakkarainen@parexel.com

Study contact

katja.hakkarainen@parexel.com

Primary lead investigator

Elani Streja

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/06/2024

Study start date

Planned: 16/09/2025

Data analysis start date
Planned: 06/02/2025

Date of final study report
Planned: 30/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

OM Pharma

Study protocol

Redacted Study Protocol - BV2023-14 - Final Version - 22 Nov 2024.pdf(1.91 MB)

BV2023-14 Study Protocol v3.0_25 March 2025_protocol amendment.pdf(1.4 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives are:

• Primary objective 1: RTI rate 12 months before and 12 and 24 months after initiating OM-85: To describe and compare the rate of RTI episodes 12 months before initiating preventive treatment with OM-85 and 12 and 24 months after the initiation.

• Primary objective 2: Comparative effectiveness – rate of RTI episodes during follow-up at 12 and 24 months: To compare the rate of RTI episodes during the follow-up at 12 and 24 months, in patients initiating preventive treatment with OM-85 and in comparable patients not initiating OM-85 (Standard Of Care/non-user group).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Broncho-vaxom, Ommunal, Broncho Munal, Vaxoral, Paxoral, Others.

Anatomical Therapeutic Chemical (ATC) code

(J07AX) Other bacterial vaccines

Other bacterial vaccines

Medical condition to be studied

Respiratory tract infection

Population studied

Short description of the study population

The overall study population will include patients aged ≥ 1 year of age with ≥ 1 Respiratory Tract Infection (RTI) episodes and no prescriptions of bacterial lysates within 12 months prior to the inclusion (baseline period). Within the overall study population, patients will be categorized to one of the two exposure groups (treatment strategies): patients who initiated OM-85 at the Cohort Entry Date (CED) or within the 30-day initiation grace period, and SOC/non-user group who did not initiate OM-85 at CED or within the 30-day initiation grace period. Subgroup analysis will be considered; if conducted, several subgroups will be defined for subgroup analyses, such as patients with respiratory comorbidities, other selected comorbidities, age, and number of previous RTI episodes in the baseline period.

Age groups

Paediatric Population (< 18 years)

Adult and elderly population (≥18 years)

Study design details

Outcomes

The primary outcome is the rate of RTI episodes.

The secondary and exploratory outcomes are:
- Baseline characteristics (age, sex, Body Mass Index, etc)
- Type and number of previous RTI episodes
- Prescription (dose, pattern of prescribing) of selected comedications, antibiotics
- Comorbidities
- Overall and RTI-specific healthcare resource utilization
- Acute exacerbations of Chronic Obstructive Pulmonary Disease (COPD)/ Chronic Bronchitis (CB) and asthma
- Time from Cohort entry date to first exacerbation of COPD/ CB and asthma

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

Inspur (China)

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

Unknown