DARWIN EU® - Uptake of meningococcal vaccines by the target population in Europe

First published: 15/07/2025

Last updated: 01/08/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000675

Study ID

1000000675

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

Immunisation against meningococcal disease forms a crucial public health measure in preventing IMD, especially amongst vulnerable populations. Nevertheless, the coverage of meningococcal vaccines within Europe remains largely unclear and inconsistent due to the variation in the vaccination schedule recommended in countries within Europe and the UK.

This study aims to generate comprehensive evidence on the coverage of MenB, MenC, and MCV4 meningococcal vaccines as part of the immunisation schedule amongst eligible individuals in Europe.

The coverage of Meningococcal vaccines will be examined in countries including Croatia, Denmark, and Finland where Meningococcal vaccines are only administered to selected individuals with specific medical need and those with increased risk of meningococcal disease due to underlying health conditions or medications rather than as part of the routine vaccination schedule.

Given the administration of meningococcal vaccines provided to individuals outside the standard age-based immunisation schedule in certain countries, this study will additionally investigate the age distribution of vaccine receivals to identify patterns of off-schedule administration in separate countries across Europe.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

- [ ] Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal

☐ Spain

☐ Sweden

☐ United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Ivan Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/03/2025

Actual: 27/03/2025

Study start date

Planned: 30/06/2025

Actual: 30/06/2025

Date of final study report
Planned: 30/10/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-006_Utilisation of Meningococcal Vaccines in Europe_V3.0.pdf (1.02 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study design:

A drug utilisation cohort study will be conducted, using routinely collected health data from seven nationwide or regional databases in six European countries

Main study objective:

1. To examine the coverage of MenB vaccines in children at age one and two years by dose received (≥1 dose, ≥2 doses, ≥3 doses, =1 dose, =2 doses, =3 doses)
2. To examine the coverage of MenC or Hib/MenC conjugate vaccines in children at age two years (≥1 dose, =1 dose)
3. To examine the coverage of MCV4 vaccines in individuals at age 18 years (≥1 dose, =1 dose)
4. To estimate the coverage of specific brand of MenB vaccines (Bexsero® and Trumemba®) in individuals aged two years and MCV4 vaccines (Menveo® and Nimenrix®) in individuals aged 18 years =
5. To characterise the age distribution of receival of MenB, MenC, and MCV4 vaccines

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Monovalent Meningococcal group B surface protein vaccine, Monovalent Meningococcal group B surface protein vaccine, Quadrivalent Meningococcal conjugate vaccine (groups A, C, W-135, and Y)

Population studied

Short description of the study population

This study will include all individuals present in their respective database who reach two years of age for examining the coverage of MenB or Hib/MenC vaccines, and 18 years of age for examining the coverage of MCV4 vaccines

---

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)

        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

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)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

The Information System for Research in Primary Care (SIDIAP)

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

InGef Research Database

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Clinical Practice Research Datalink (CPRD) GOLD

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown