# 205514 (V72_38OB) - Post-licensure observational effectiveness study of meningococcal B vaccine 4CMenB (Bexsero®) vaccination

**First published:** 28/07/2015

**Last updated:** 02/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS10416

**Study ID**

33821

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

The purpose of this study is to investigate the effectiveness of 4CMenB vaccination during routine clinical care in the UK national immunisation programme (NIP).

**Study status**

Finalised

## Research institutions and networks

### Institutions

Public Health England (PHE)

## Contact details


**Study institution contact**

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

**Study contact**

Vx.publicdisclosureglobal@gsk.com

**Primary lead investigator**

Call Center EU Clinical Trials

**Primary lead investigator**


## Study timelines

**Date when funding contract was signed**
Actual: 02/11/2011

**Study start date**
Actual: 01/09/2015

**Data analysis start date**
Actual: 01/10/2015

**Date of final study report**
Actual: 24/05/2019

## Sources of funding

- Other

## More details on funding

This surveillance was conducted by Public Health England. Post-marketing surveillance reports were provided to GSK to comply with their Risk Management Strategy.GSK provided funding for purchasing the reports and provided the MATS kits.See section 19

## Study protocol

V72_38OB-04 Trial Registration Form-ENCePP Registration Redacted Protocol-2015-07-03.pdf (622.26 KB)

gsk-205514-protocol-redact.pdf (597.14 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

**Main study objective:**

The objective of this post-marketing observational study is to assess the impact on MenB and effectiveness of 4CMenB vaccination against MenB disease, after

introduction of 4CMenB in the UK

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Descriptive study, Vaccine effectiveness (VE) will be assessed by the screening method, or by a case-control method if the screening method cannot be used (for example, if appropriate coverage data cannot be determined)

## Study drug and medical condition

**Medicinal product name**

BEXSERO

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

RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NHBA FUSION PROTEIN
RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NADA PROTEIN
RECOMBINANT NEISSERIA MENINGITIDIS GROUP B FHBP FUSION PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE
OUTER MEMBRANE VESICLES FROM NEISSERIA MENINGITIDIS GROUP B (STRAIN NZ 98/254)
NEISSERIA MENINGITIDIS

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**Anatomical Therapeutic Chemical (ATC) code**

(J07AH09) meningococcus B, multicomponent vaccine

meningococcus B, multicomponent vaccine

# Population studied

**Short description of the study population**

General population in England.

Individuals were included in the cohorts targeted for vaccination in England.

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**Age groups**

- Infants and toddlers (28 days – 23 months)

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**Estimated number of subjects**

1

# Study design details

**Outcomes**

The primary outcome is a capsular group B confirmed case by culture and/or PCR from a normally sterile site (case definition A), regardless of MATS, The secondary outcome is a confirmed or probable case of capsular group B 4CMenB-vaccine-type where protection would have been expected based on the vaccine antigens (case definition B)

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**Data analysis plan**

VE = 1 - (PCV x (1-PPV)) / ((1-PCV) x PPV)VE: Vaccine EffectivenessPCV: Proportion Cases VaccinatedPPV: Proportion Population Vaccinated

# Documents

**Study, other information**

Sources of funding information.pdf (70.55 KB)

**Study publications**

Ladhani SN, Andrews N, Parikh SR, Campbell H, White J, Edelstein M, Bai X, Luci…

# 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)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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