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

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

Name of medicine

BEXSERO

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

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.

Age groups

Infants and toddlers (28 days – 23 months)

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)

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

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