A non-interventional, open observational non-inferiority study in two cluster-assigned cohorts of children aged 14 months into the safety of NeisVac-C® vaccines manufactured at two different production sites and given simultaneously with measles-mumps-rubella vaccine, assessed by web-based intensive monitoring (Peuterprik)

First published: 05/03/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5937

Study ID

19783

DARWIN EU® study

No

Study countries

Netherlands

Study description

Non-interventional, open observational non-inferiority study with two cluster-assigned cohorts of toddlers (14 months old) who receive at vaccination centers NeisVac-C® vaccination with either - “old” lots produced in Beltsville (group B), or - “new” lots from Orth/Donau (group A), simultaneously with MMR vaccine. Clusters are assigned at the level of vaccination centers.From 4 full days after the vaccines were administered, parents will receive web-based questionnaires with questions about any ADRs that occurred after vaccination.

Study status

Finalised

Research institutions and networks

Institutions

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Outdated | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Hans C Rumke info@lareb.nl

Study contact

info@lareb.nl

Primary lead investigator

Eugene van Puijenbroek

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/12/2013

Study start date

Planned: 01/07/2014

Actual: 01/07/2014

Data analysis start date

Planned: 30/06/2016

Actual: 31/05/2016

Date of final study report

Planned: 30/09/2016

Actual: 01/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc (formerly Baxter GmbH)

Study protocol

Study Protocol Peuterprik-Version1.2-15jan14.pdf (283.87 KB)

Study Protocol Peuterprik-Version1 4-Amendment2-21JUL2015.pdf (698.64 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:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

to compare the proportions of vaccinees with fever of ≥38ºC within 4 days after injections of the Baxter NeisVac-C® vaccine bulk material produced in Orth/Donau (new, group A) or NeisVac-C® vaccine of which the bulk material was produced in Beltsville (old, group B), and simultaneous MMR vaccine for both groups of NeisVac-C® recipients

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Name of medicine, other

Population studied

Short description of the study population

Healthy toddlers aged 13-18 months old, eligible to receive MenC and MMR vaccinations according to the Netherlands Immunisation Programme.

Age groups

Infants and toddlers (28 days – 23 months)

Estimated number of subjects

2430

Study design details

Outcomes

Proportions of children with fever (rectally measured body temperature of ≥38.0°C) within 4 days after vaccination with NeisVac-C® and MMR.
Proportions of children with solicited other systemic and local reactions within 4 days after vaccination with NeisVac C® and MMR.

Data analysis plan

The primary endpoint of the study, fever cases observed within 4 days after vaccination will be analyzed using logistic regression with vaccination groups (“old” / “new” product) and potential confounders as listed in 5.3 as explanatory factors, applying a log link in order to obtain relative risk estimates at the end. Relative risk and its 95% CI of occurrence of fever cases with the “new” and “old” NeisVac-C® product will be calculated from the regression model assessing a potential increase of fever reactions with the “new” product.

If the upper limit of the 95% CI is below 1.5 then the “new” product is considered to be non-inferior to the old one as far as fever reaction is concerned.The secondary endpoints will be analyzed similarly and descriptive without the non-inferiority considerations.

Documents

Study results

PP NeisVacC Study Report Final version 1-1AUG2016.pdf (730.17 KB)

SUMMARY PP NeisVacC Study Final version 1-1AUG2016.pdf (248.51 KB)

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Declaration of interest-signed-24FEB14.pdf (460.31 KB)

Composition of steering group and observers

Steering Group and Observers Peuterprik onderzoek-5MAR14.pdf (4.63 KB)

Signed code of conduct

Annex 3 signed-24FEB14.pdf (225.73 KB)

Signed code of conduct checklist

Annex 2 signed 12Mar2014 (1).pdf (579.58 KB)

Signed checklist for study protocols

Checklist for Study Protocol signed-24FEB14.pdf (651.11 KB)

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

Unknown