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

PURI

https://redirect.ema.europa.eu/resource/19783

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 | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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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

NeisVac-C

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

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