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





# 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

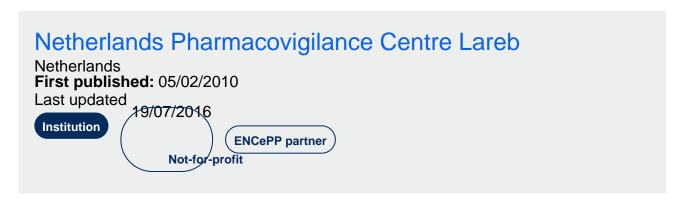
Non-interventional, open observational non-inferiority study with two cluster- assigned cohorts of toddlers (14 months old) who receive at vaccination centers NeisVac-C® vaccination with either - "old" lots produced in Beltsville (group B), or - "new" lots from Orth/Donau (group A), simultaneously with 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 institution and networks

# Institutions



# Contact details

Study institution contact

Hans C Rumke

Study 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

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#### 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 data collection

### Main study objective:

to compare the proportions of vaccinees with fever of ?38°C 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

## Signed checklist for study protocols

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

## Data sources

## **Data sources (types)**

Administrative data (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