

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 institution 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

Hans C Rumke

Study contact

[info@lareb.nl](mailto:info@lareb.nl)

### Primary lead investigator

Eugene van Puijenbroek

Primary lead investigator

## Study timelines

Date when funding contract was signed

Actual:  
05/12/2013

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#### **Study start date**

Planned:  
01/07/2014  
Actual:  
01/07/2014

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#### **Data analysis start date**

Planned:  
30/06/2016  
Actual:  
31/05/2016

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#### **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

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary data collection

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**Main study objective:**

to compare the proportions of vaccinees with fever of  $\geq 38^{\circ}\text{C}$  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

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**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.

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## Age groups

Infants and toddlers (28 days – 23 months)

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## Estimated number of subjects

2430

# Study design details

## Outcomes

Proportions of children with fever (rectally measured body temperature of  $\geq 38.0^{\circ}\text{C}$ ) 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.

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## 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 descriptively 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)

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## Data management

## ENCePP Seal

This study has been awarded the ENCePP seal



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**Conflicts of interest of investigators**

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

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**Composition of steering group and observers**

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

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**Signed code of conduct**

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

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**Signed code of conduct checklist**

[Annex 2 signed 12Mar2014 \(1\).pdf](#)(579.58 KB)

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**Signed checklist for study protocols**

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

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## 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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown