Immunological response after early extra and regular MMR immunization; 6 years follow-up

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26839

Source Nationaal Trial Register

Brief title Early extra MMR immunization; 6 years follow-up

Health condition

Measles infection, paramyxovirus

Sponsors and support

Primary sponsor: RIVM **Source(s) of monetary or material Support:** RIVM, Ministry of Health, Welfare and Sport

Intervention

Outcome measures

Primary outcome

To assess the effect of early extra measles immunization on the humoral immunity against measles 6 years after

MMR-1 at 14 months of age

Secondary outcome

•Determine the effect of early extra measles immunization on the immunity against mumps and rubella 6 years after

MMR-1 at 14 months of age

•Determine the effect of early extra measles immunization on the immunity against other NIP vaccines 6 years after

MMR-1 at 14 months of age

Study description

Background summary

From May 2013 until March 2014, a measles epidemic occurred in the Netherlands. During this epidemic, the Dutch Ministry of Health decided to offer infants between 6 and 12 months of age, living in the measles outbreak area, an early extra MMR (MMR-0) immunization. We previously investigated the immunological response to early vaccination in a cohort of these children up to 4 years of age (NL45616.094.13/IIV-273). The first outcome was that all children who received an early extra MMR-0 vaccination between 6-12 months of age showed a measles antibody response. A large part of these children had protective measles levels (≤ 0.12 IU/ml) at the age of 14 months. These children were protected during the measles epidemic. After the regular MMR-1 vaccination at 14 months of age, almost all children had protective levels (both in the early extra MMR-0 group as in the regular MMR-1 group). Three years later in part of the early extra MMR-0 vaccinated children measles antibody levels dropped below the protective threshold, while all regular MMR-1 vaccinated children still had protective measles levels. This steeper decline of measles antibody levels will be monitored in the current study. We will measure further decline in measles specific (functional) antibody concentration and the proportion of children with antibodies below the cut-off for clinical protection 6 years after the MMR-1 vaccination.

Study objective

We will measure further decline in measles specific (functional) antibody concentration and

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the proportion of children with antibodies below the cut-off for clinical protection 6 years after the MMR-1 vaccination.

Study design

6 years post MMR-1

Contacts

Public RIVM Alienke Wijmenga-Monsuur

NA Scientific RIVM Alienke Wijmenga-Monsuur

NA

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Participation in the study on the immunological effects of early measles vaccination, as described in a separate study protocol (NL45616.094.13/IIV-273)

• The parents/legally representatives accept participation in the trial according to the described procedures

- Presence of a signed informed consent
- Children must have received their NIP vaccinations according to schedule.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Receiving immunosuppressive medication

• Presence of a serious disease that requires medical care that can interfere with the results

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of the study

- Known or suspected immunological disorder
- Bleeding disorders

Study design

Design

Observational non invasive
Parallel
Non-randomized controlled trial
Open (masking not used)
Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	22-09-2019
Enrollment:	105
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date: Application type:

18-09-2019 First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48447 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8035
ССМО	NL69434.100.19
OMON	NL-OMON48447

Study results