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

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Primary Objective: To assess the effect of early extra measles immunization on the humoral immunity against measles 6 years after MMR-1 at 14 months of ageSecondary Objective(s): •Determine the effect of early extra measles immunization on the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON48447

Source
ToetsingOnline

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

Condition

- Viral infectious disorders

Synonym
Measles infection, paramyxovirus

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van VWS

Intervention

Keyword: Early vaccination, Measles, MMR, Outbreak

Outcome measures

Primary outcome

• Measles specific serum neutralizing antibodies 6 years after MMR-1 at 14

months of age

Secondary outcome

• Measles specific serum IgG antibody and avidity (Luminex), and functional

antibody characteristics prior 6 years after MMR-1 at 14 months of age

• Serum IgG antibody concentrations against mumps and rubella (Luminex) 6 years

after MMR-1 at 14 months of age

• Antibodies 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 [1, 2]) 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

Primary Objective:
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 Objective(s):
•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 design

Additional follow-up of a controlled open parallel group trial of children who were previously included in a study on the immunological effects of early extra MMR-0

In this follow-up study, a single blood sample will be collected, by finger stick, of children who previously were immunized with an early extra MMR-0 and the regular MMR-1 at 14 months of age, and infants of a control group who only received the regular MMR-1 at 14 months of age. Blood sampling through a finger-stick will be performed during a home visit at 6 years post MMR-1 (±6 months). Alternatively, if preferred by the parents, they can perform the finger-stick on their child and send in the blood.

Study burden and risks

In this study, we follow the children who previously participated in the EMI study (children who received an extra early MMR-0 vaccination where compared to children who only received the regular MMR-1 vaccination, NL45616.094.13/IIV-273). The children have no direct benefit from participating in the study. Blood collection will be done using a finger-stick, which poses no risk. The follow-up will gain insight in the antibody levels at 6 years after MMR-1 in early extra MMR-0 vaccinated children and regular MMR-1 vaccinated children. We already have immunological data from these children from our previous study to compare these results with, and therefore they are the only possible participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

•Previous 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

•Receiving immunosuppressive medication
•Presence of a serious disease that requires medical care that can interfere with the results of the study

•Known or suspected immunological disorder
•Bleeding disorders

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2019
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	29-05-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26839
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69434.100.19
OMON	NL-OMON26839