Immunological response after early extra and regular MMR immunization; 10 years follow-up

Published: 14-09-2023
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Primary Objective: - To assess the effect of MMR-0 vaccination on the humoral immunity against measles 2 years (+/- 2 months) after MMR-2 vaccination.Secondary Objective(s): - Determine the effect of MMR-0 vaccination on the humoral immunity against...

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

Summary

ID

NL-OMON56402

Source
ToetsingOnline

Brief title
Early extra MMR immunization; 10 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 IgG and virus neutralizing antibodies 2 years (+/- 2

months) after MMR-2 vaccination.

Secondary outcome

Serum IgG antibody concentrations against mumps and rubella 2 years (+/- 2

months) after MMR-2 vaccination.

Study description

Background summary

The latest epidemic lasted from May 2013 until March 2014. The Outbreak Management Team (OMT) of the RIVM at that time advised to administer an early extra measles, mumps and rubella (MMR-0) immunization during this outbreak, to protect children below one year of age in areas with lower immunization coverage (less than 90%) and thus with higher risk of exposure to measles virus. To monitor the long term immunological effects of this outbreak measure, a clinical study was performed (NL45616.094.13/IIV-273). In this study, children who received the MMR-0 vaccination between 6 and 12 months of age in addition to the regular vaccination at 14 months of age were compared to a control group of children who only received the regular vaccination at 14 months of age. Most children who received an MMR-0 vaccination between 6-12 months of age showed a measles antibody response and were regarded to be protected during the measles epidemic. A small percentage of the children who received MMR-0 between 6 and 8 months of age (~12%) had measles IgG levels below the threshold of protection (<=0.12 IU/ml) at 14 months of age prior to MMR-1 vaccination. After the regular MMR-1 vaccination at 14 months of age, all children had gained protective antibody levels, both in the MMR-0 group and in the regular MMR-1 group. Three years later, measles antibody levels dropped below the protective threshold in 11% of the 6-8 months MMR-0 vaccinated children, while all of the 9-12 months MMR-0 vaccinated children and children who only received the regular MMR-1 dose still had protective measles levels. At 6-7 years of age, this percentage had increased to 68%. Among the children

who received an MMR-0 dose between 9 and 12 months of age and the children of the control group who only received their regular MMR-1 at 14 months of age, 21% and 11% respectively, had dropped below the threshold of protection [preliminary data].

Study objective

Primary Objective:
- To assess the effect of MMR-0 vaccination on the humoral immunity against measles 2 years (+/- 2 months) after MMR-2 vaccination.

Secondary Objective(s):
- Determine the effect of MMR-0 vaccination on the humoral immunity against mumps and rubella 2 years (+/- 2 months) after MMR-2 vaccination.

Exploratory Objective(s):
- Determine the effect of MMR-0 vaccination on the functionality and isotype distribution of antibodies against measles 2 years (+/- 2 months) after MMR-2 vaccination.

Study design

In this follow-up study, a single small blood sample will be collected by finger-stick, of children who previously were immunized with an MMR-0 vaccination between 6-12 months of age, and children 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 at 2 years (+/- 2 months) post MMR-2 vaccination. Parents can perform the finger-stick on their child themselves and mail the blood sample to the RIVM. If parents do not feel comfortable performing the finger-stick themselves, an alternative can be arranged. Furthermore, a digital questionnaire is filled out with questions about the health of the child and other vaccinations.

Study burden and risks

In this study, we follow the children who previously participated in the EMI study (children who received an MMR-0 vaccination were compared to children who only received the regular MMR-1 vaccination, NL45616.094.13/IIV-273 and NL69434.100.19 / IIV-411) or in the BMR-nul questionnaire study. 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 2 years (+/- 2 months) after MMR-2 vaccination in MMR-0 vaccinated children and regular MMR-1 vaccinated children. We already have immunological data from these children from our previous studies 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

• Participation in the study on the immunological effects of early extra measles vaccination, as described in a separate study protocol (NL45616.094.13/IIV-273) or participation in the BMR-nul questionnaire study
• The parents/legally representatives accept participation in the trial according to the described procedures
• Presence of an informed consent signed by both parents/legal representatives
• Children must have received the MMR-2 vaccination

Exclusion criteria

• 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:	Completed
Start date (anticipated):	30-10-2023
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	14-09-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	27-02-2024
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
Other	ISRTCN
CCMO	NL84855.100.23