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

Gepubliceerd: 18-09-2019 Laatst bijgewerkt: 19-03-2025

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26839

Bron
Nationaal Trial Register

Verkorte titel
Early extra MMR immunization; 6 years follow-up

Aandoening

Measles infection, paramyxovirus

Ondersteuning

Primaire sponsor: RIVM
Overige ondersteuning: RIVM, Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

6 years post MMR-1

Contactpersonen

Publiek

RIVM
Alienke Wijmenga-Monsuur

NA

Wetenschappelijk

RIVM
Alienke Wijmenga-Monsuur

NA

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 of the study
• Known or suspected immunological disorder
• Bleeding disorders

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-09-2019
Aantal proefpersonen:	105
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48447
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten