Third MMR vaccine dose in young adults

Gepubliceerd: 22-06-2016 Laatst bijgewerkt: 15-05-2024

In 1987, MMR vaccination was implemented in the national immunization program of the Netherlands (NIP) by offering vaccinations to children at the age of 14 months and 9 years. Consequently, the annual mumps incidence decreased dramatically, not...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20600

Bron
Nationaal Trial Register

Verkorte titel
BMR-3

Aandoening

MMR vaccination
Mumps, Measles and Rubella
Mumps outbreak
Immunogenicity and tolerance
Antibody response and cellular immunity
BMR vaccinatie
Bof, Mazelen en Rode Hond
Bof uitbraak
Immunogeniciteit en veiligheid
Antistof respons en cellulaire immuniteit

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment (RIVM), Centre for Infectious Disease Control (CIb)
Overige ondersteuning: Ministry of Health, Welfare and Sports

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameters are the mumps-specific VN antibody concentrations (against the vaccine- and currently circulating mumps virus strains) and IgG antibody concentrations (including antibody avidity) measured in serum samples taken prior to, and 10 days, 4 weeks, 1 year and 3 years following a third vaccine dose of MMR in healthy young adults (18-25 years).

Toelichting onderzoek

Achtergrond van het onderzoek

In 1987, MMR vaccination was implemented in the national immunization program of the Netherlands (NIP) by offering vaccinations to children at the age of 14 months and 9 years. Consequently, the annual mumps incidence decreased dramatically, not only in the Netherlands, but also in other countries where mumps vaccination was implemented. However, in the past two decades large mumps outbreaks were reported in various countries despite routine MMR vaccination mainly affecting young adults that have been vaccinated twice. Also in the Netherlands, since 2004, several mumps outbreaks among vaccinated persons have occurred, despite high vaccination coverage of 96% and 93%, respectively, for the first and second MMR dose. The main explanations for the re-emergence of mumps in vaccinated populations are waning of vaccine-induced immunity and resurgence of specific wild type mumps virus strains (e.g. genotype G5), possibly due to antigenic differences. Vaccinated young adults (18-25 years), and in particular students, who have acquired immunity against mumps solely by vaccination and not by previous wild-type mumps virus infection, appear to be most prone for mumps infection. The fact that close social contact facilitates virus transmission combined with import of mumps cases via student exchange programmes from countries were mumps is still endemic further increases the risk for this population. Mumps outbreak control so far has been restricted to offering MMR vaccination to non- or incompletely vaccinated individuals. A third dose of MMR could be an effective intervention to control outbreaks among vaccinated persons, but sufficient evidence regarding immunogenicity and effectiveness is currently lacking. For this purpose, the short- and long-term mumps-specific humoral and cellular immunity induced following a third dose of MMR vaccine will be investigated. The study population will consist of 150 healthy young adults aged 18-25 years who have received the first two MMR doses at the age of 14 month and 9 years, and have no history of mumps disease and/or have not lived in a household with anyone who has had mumps disease. They receive a third dose of the MMR vaccine intramuscular (i.m.). Blood will be collected prior to, 10 days, 4 weeks, 1 year and 3 years following a third vaccine dose of MMR. Saliva is collected prior to, 4 weeks and 1 year

following a third vaccine dose of MMR.

Doel van het onderzoek

In 1987, MMR vaccination was implemented in the national immunization program of the Netherlands (NIP) by offering vaccinations to children at the age of 14 months and 9 years. Consequently, the annual mumps incidence decreased dramatically, not only in the Netherlands, but also in other countries where mumps vaccination was implemented. However, in the past two decades large mumps outbreaks were reported in various countries despite routine MMR vaccination mainly affecting young adults that have been vaccinated twice. Also in the Netherlands, since 2004, several mumps outbreaks among vaccinated persons have occurred, despite high vaccination coverage of 96% and 93%, respectively, for the first and second MMR dose. Mumps outbreak control so far has been restricted to offering MMR vaccination to non- or incompletely vaccinated individuals. A third dose of MMR could be an effective intervention to control outbreaks among vaccinated persons, but sufficient evidence regarding immunogenicity and effectiveness is currently lacking. For this purpose, the short- and long-term mumps-specific humoral and cellular immunity induced following a third dose of MMR vaccine will be investigated in young adults.

Onderzoeksopzet

prior to, and 10 days, 4 weeks, 1 year and 3 years following a third vaccine dose of MMR

Onderzoeksproduct en/of interventie

M-M-RVAXPRO

Contactpersonen

Publiek

RIVM
Alienke Wijmenga-Monsuur
Rijksinstituut Volksgezondheid en Milieu
A. van Leeuwenhoeklaan 9
Bilthoven 3720 BA
The Netherlands
NA

Wetenschappelijk

RIVM
Alienke Wijmenga-Monsuur

Rijksinstituut Volksgezondheid en Milieu
A. van Leeuwenhoeklaan 9
Bilthoven 3720 BA
The Netherlands
NA

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy young adult 18-25 years of age

2. Previously been immunized with two doses of the MMR vaccine according to the Dutch NIP (MMR-1 at ~14 months and MMR-2 at ~9 years)

3. Willing to adhere to the protocol and perform all planned visits and all sample collections

4. Presence of a signed informed consent (after receiving oral and written information)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medical conditions that will severely affect immunological responses to vaccinations, such as, but not limited to, cancer or an immune disorder.

2. Vaccination should be postponed during any illness with fever >38.5°C until the fever has disappeared.

3. Vaccination with any vaccine during the first two weeks before and four weeks after MMR-3

4. An additional MMR vaccination during the study

5. Coagulation disorder and/or anticoagulant medication

6. Be or have been under immunosuppressive medical treatment, like cytostatics, highdose corticosteroids, immune globulins, blood or plasma transfusions that might interfere with the results of the study (within the previous 3 months)

7. Have or previously had clinical symptoms of mumps virus infection

8. Have or previously had cases of mumps disease within your household

9. Had experienced a previous severe adverse reaction to any vaccine

10. Being pregnant; Furthermore, pregnancy should be avoided for 1 month following vaccination

11. Breast-feeding women

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47906
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5674
NTR-old	NTR5911
CCMO	NL57282.094.16
OMON	NL-OMON47906

Resultaten

Samenvatting resultaten
https://pubmed.ncbi.nlm.nih.gov/33269296/
https://pubmed.ncbi.nlm.nih.gov/34211021/
https://pubmed.ncbi.nlm.nih.gov/31112277/