Third MMR vaccine dose in young adults

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20600

Source
Nationaal Trial Register

Brief title
BMR-3

Health condition

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

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM), Centre for Infectious Disease Control (CIb)
Source(s) of monetary or material Support: Ministry of Health, Welfare and Sports

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

-Frequency and intensity of the local and systemic adverse events

- Mumps-specific IgA and IgG (saliva) prior to, and 4 weeks and 1 year following a third vaccine dose of MMR

- The presence and frequency of mumps-specific memory and effector T- and B-cells in peripheral blood following MMR-3, in a voluntary subset of the participants prior to, 4 weeks and 1 year following a third vaccine dose of MMR

-Serum IgG response against measles and rubella (components of the MMR vaccine) prior to, 10 days, 4 weeks, 1 year and 3 years following a third vaccine dose of MMR

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

M-M-RVAXPRO

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-06-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47906
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
https://pubmed.ncbi.nlm.nih.gov/33269296/
https://pubmed.ncbi.nlm.nih.gov/34211021/
https://pubmed.ncbi.nlm.nih.gov/31112277/