Immunogenicity and safety study of a third measles mumps rubella (MMR-3) vaccine dose in healthy young adults in The Netherlands

Published: 23-05-2016
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Primary objective: * The main objective is to assess the effect of third dose of MMR (MMR-3) in young adults 18-25 years of age on the development and duration of mumps-specific serum virus neutralization (VN) and IgG antibody concentrations (...

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

Summary

ID

NL-OMON47906

Source
ToetsingOnline

Brief title
Third MMR vaccine dose in young adults (acronym: MMR-3)

Condition

- Viral infectious disorders

Synonym
Mumps infection, parotitis

Research involving
Human

Sponsors and support

Primary sponsor: RIVM

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

Intervention

Keyword: Immunogenicity, Mumps, Safety, Vaccine

Outcome measures

Primary outcome

* 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

Secondary outcome

* Frequency and intensity of the local and systemic adverse events

* Mumps-specific IgA and IgG (saliva) prior to, 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 (n=30) 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 in young adults.

Study objective

Primary objective:
* The main objective is to assess the effect of third dose of MMR (MMR-3) in young adults 18-25 years of age on the development and duration of mumps-specific serum virus neutralization (VN) and IgG antibody concentrations (including antibody avidity) between 10 days to 3 years following MMR-3.

Secondary objectives:
* To assess the local and systemic tolerance of MMR-3.
* To assess the short- and long-term (4 weeks and 1 year) mumps-specific IgA and IgG levels (in saliva) following MMR-3
* To explore the presence and frequency of mumps-specific memory and effector T- and B-cells in venous blood, 4 weeks and 1 year after MMR-3
* To assess IgG response (10 days, 4 weeks, 1 year and 3 years) against measles and rubella following MMR-3.

Study design

An interventional, longitudinal, prospective study.

Intervention

All participants will receive an extra MMR vaccination (intramuscularly) at visit 1.

Study burden and risks

Available data on a third dose of MMR vaccine in young adults does not suggest any elevated frequency or unusual patterns of adverse events compared to the first and second MMR immunizations given within the routine national immunization program (RVP).

From all participants blood and saliva samples will be collected.
Blood collection is harmless but may be slightly painful and can cause a bruise at the injection site.
Saliva sampling is easy and without adverse effects in the experience of the research team.

The benefit for the subjects to participate in this study is that they might be better protected against mumps and its complications, because of the additional vaccination against mumps.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy young adult 18-25 years of age., 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).

Exclusion criteria

Medical conditions that will severely affect immunological responses to vaccinations, such as, but not limited to, cancer or an immune disorder., Vaccination should be postponed during any illness with fever >38.5°C until the fever has disappeared., Vaccination with any vaccine during the first two weeks before and four weeks after MMR-3., An additional MMR vaccination during the study., Coagulation disorder and/or anticoagulant medication. , Be or have been under immunosuppressive medical treatment, like cytostatics, high-dose corticosteroids, immune globulins, blood or plasma transfusions that might interfere with the results of the study (within the previous 3 months)., Have or previously had clinical symptoms of mumps virus infection., Have or previously had cases of mumps disease within your Household., Had experienced a previous severe adverse reaction to any vaccine. , Being pregnant; Furthermore, pregnancy should be avoided for 1 month following vaccination. , Breast-feeding women.

Study design

Design

Study phase:	4
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-10-2016
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	M-M-RVAXPRO

Ethics review

Approved WMO Date:	23-05-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-06-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2019
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	25-09-2019
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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: 20600
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-001104-36-NL
CCMO	NL57282.094.16

Study results

Date completed:	25-03-2020
Results posted:	18-09-2020
Actual enrolment:	150

First publication
01-01-1900

URL result
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