Immunological correlates of protection against measles

Published: 23-12-2008
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To identify serological correlates of protection against clinical measles and measles virus infection in once vaccinated children.

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

Summary

ID

NL-OMON32077

Source
ToetsingOnline

Brief title
MMR1 study

Condition

- Viral infectious disorders

Synonym
immunity measles

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: children once MMR vaccinated, immunity, measles, outbreak

Outcome measures

Primary outcome

* Identification of serological (measles neutralizing antibodies and IgG)

correlates of protection against clinical measles and measles virus infection.

Secondary outcome

* To study a measles IgG correlate for protection in oral fluid;

* To describe measles compatible symptoms among once vaccinated individuals who

seroconvert to measles but do not meet the clinical case definition

(*attenuated measles*);

* To assess the attack rate of measles symptoms in the study population.

* To assess the degree of underdiagnosis, underreporting and the burden of

disease of measles in the study population.

Study description

Background summary

Measles is of global public health importance due to its high burden of morbidity and mortality and its extreme infectiousness. A safe and effective vaccine is available to prevent measles. To assess the prevalence of immunological protection against measles, quantitative IgG antibody levels are usually compared with a cut-off level indicating protection. The correlate for protection used for this is, however, based on a very limited set of data. In the Netherlands, a measles outbreak among individuals refusing vaccination is ongoing. Based on observations during the previous outbreak in this group, a substantial number of once vaccinated individuals in the vicinity of the outbreak will also develop measles. This offers a unique opportunity to study immunological correlates of protection against measles virus infection and disease in vaccinated individuals. These correlates are necessary for assessing the population*s immunity, and guide the development of new measles vaccination strategies.

Study objective

To identify serological correlates of protection against clinical measles and measles virus infection in once vaccinated children.

Study design

Observational study. In the study population we will administer a questionnaire before and after the outbreak. This information will be used to assess the attack rate of measles in this population. A subset of participants will be invited for microbiological sampling prior to and after the outbreak. In this subset we will correlate immunological findings with occurrence of measles and measles virus infection.

Intervention

interventie

Study burden and risks

Parents of all participating children will be asked to twice fill in a short questionnaire (before and after the outbreak). Parents of a subset of children will be invited to twice attend a dedicated study clinic with their child. The clinic will be located close to their residence or at the school of their child or at home. They receive additional information about the study and are requested to fill in an informed consent form. At the first visit to the clinic (prior to the outbreak) a venous blood sample (4 ml) and an oral fluid sample will be taken from the child. At the second visit (after the outbreak) a finger stick blood sample (200 µl) and an oral fluid sample will be taken from the child. Risks associated with these sampling methods are negligible. Filling in the questionnaires will take about 10 minutes per questionnaire. Participants who attend for microbiological sampling will receive a gift voucher (*VVV-bon*) of ¤10 for each of the two visits to the clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children aged 4 - 8 years

Exclusion criteria

Children twice vaccinated with MMR vaccination

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	15-07-2013
Enrollment:	750
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	23-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-07-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-08-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
CCMO	NL22617.041.08