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Early extra measles immunisation during a measles outbreak

Submission date
06/05/2024

Recruitment status
Not yet recruiting

Registration date
20/08/2024

Overall study status
Ongoing

Last Edited
18/07/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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) vaccination during this outbreak, to protect children below 1 year of age in areas with lower vaccination coverage (less than 90%) and thus with higher risk of exposure to measles virus. In the past year, measles re-emerged in several European countries, which includes Romania, Morocco, France, Austria and the UK. Recently, a few cases were reported in the Netherlands. So far, these confer import infections, but a measles outbreak can be expected to occur in the Netherlands.
Researchers previously investigated the immunological response to early vaccination in a group of MMR-0 vaccinated children and a control group. Blood samples were taken at the age of 14 months, 2-8 months after MMR-0 vaccination. About 12% of the children who received MMR-0 between 6 and 8 months of age had no detectable antibodies at 14 months of age before MMR-1. We do not know whether these children have not responded to the MMR-0 vaccination, possibly due to interference of maternal antibodies, or if the immune response after MMR-0 vaccination has decreased quickly over time.
The aim of this study is to determine the immune response to MMR-0 vaccination given to infants younger than 14 months of age in a measles outbreak setting. Blood samples will be obtained before and 4 weeks after MMR-0 vaccination and before, 4 weeks after and 1 year after MMR-1 vaccination. Also, the presence of maternal antibodies before MMR-0 vaccination will be determined to investigate the effect of maternal antibodies on the child's immune response to MMR-0 vaccination.

Who can participate?
1. Children aged 6 to 12 months who will receive an MMR-0 vaccination (MMR-0 group)
2. Children aged 14 months who will receive an MMR-1 vaccination and have not received an MMR-0 vaccination and have not encountered measles infection (control group)
3. Biological mothers of MMR-0 vaccinated children participating in our study

What does the study involve?
For MMR-0 vaccinated children: five blood samples are obtained by heelstick or fingerstick and three short questionnaires are completed.

For the children in the control group, three blood samples are obtained by heelstick or fingerstick and two short questionnaires are completed.
For the biological mothers of MMR-0 vaccinated children: one blood sample is obtained by fingerstick and one short questionnaire is completed.

What are the possible benefits and risks of participating?
The participants have no direct benefit from participating in the study. Blood collections will be done using a heelstick or fingerstick, which poses a low risk. Optionally, blood collections can be done by venepunctures when parents have consented.

Where is the study run from?
Dutch National Institute of Health and the Environment (RIVM) (Netherlands)

When is the study starting and how long is it expected to run for?
Undetermined. The study will start as soon as there is an outbreak of measles in the Netherlands and as soon as the Dutch Ministry of Health, Welfare and Sport decides to implement early measles vaccination as an outbreak control measure.

Who is funding the study?
The Dutch Ministry of Health, Welfare and Sport (Netherlands)

Who is the main contact?
elmo@rivm.nl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2024-513395-18

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

IIV-671

Study information

Scientific Title
EarLy extra Measles immunisation during a measles Outbreak

Acronym
ELMO

Study objectives
The main objective is to determine the humoral immune response to MMR-0 immunisation given to infants younger than 14 months of age in a measles outbreak setting. Secondary objectives are to determine the influence of maternal antibodies on the humoral response to the MMR-0 immunisation and to determine the effect of the MMR-0 immunisation on the immune response to MMR-1 immunisation. Furthermore, the reactogenicity of the MMR immunisations will be determined as an indication of vaccine responsiveness. Also, immunogenicity of the MMR-0 immunisation against measles, mumps and rubella will be determined.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/07/2024, Medical research Ethics Committees United (Postbus 2500, Nieuwegein, 3430 EM, Netherlands; +31 88 3208784; info@mec-u.nl), ref: 2024-513395-18-00

Study design
Interventional non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Measles infection in children

Interventions
Participation in this study entails five heel- or fingerstick blood collections of 250-500 µl for the MMR-0 group and three heel- or fingerstick blood collections of 250-500 µl for the control group. Optionally, five or three venepunctures of 4 ml per sampling time point are performed, respectively, if parents decide to participate in the cellular immunity part of this study. To gain a better insight in the maternal antibodies in the child, the biological mothers of MMR-0 immunised children will be asked for an optional blood sample by fingerstick of 300-800 µl.

Intervention Type
Biological/Vaccine

Phase

Phase IV

Drug/device/biological/vaccine name(s)
measles, mumps and rubella vaccine (M-M-RvaxPro)

Primary outcome(s)
Measles specific virus neutralising antibody concentrations 4 weeks mesured by blood sample post MMR-0 immunisation

Key secondary outcome(s))
Measured by blood sample:
1. Measles specific maternal antibody concentrations prior to MMR-0 immunisation.
2. Measles specific virus neutralising antibody concentrations prior to, 4 weeks post and 1 year post MMR-1 immunisation in MMR-0 immunised children and a control group.
3. Assess MMR vaccination induced reactogenicity after MMR-0 and MMR-1 as an indication for vaccine responsiveness.
4. Serum binding IgG antibody concentrations against measles, mumps and rubella prior to and 4 weeks post MMR-0 and prior to, 4 weeks post and 1 year post MMR-1 in MMR-0 immunised children and a control group.

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Infants eligible for an MMR-0 immunisation and willing to receive the MMR-0 immunisation or having received the MMR-0 immunisation less than 4 weeks ago (MMR-0 group only)
2. Infants willing to receive the MMR-1 immunisation at 14 months of age (control group)
3. Infants have to be healthy according to the same health criteria applied in the well baby clinic when a child is immunised, e.g. also children with small increases in body temperature or a cold are seen as children with normal health
4. The parents/legally representatives accept participation in the study according to the described procedures
5. Presence of a signed informed consent (the parents/legally representatives have given written informed consent after receiving oral and written information)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit

15 months

Sex
All

Key exclusion criteria
1. Confirmed measles infection before study entry
2. Having received an MMR immunisation (control group only)
3. Contra-indications as mentioned in the SmPC of the vaccine, such as expected allergy or hypersensitivity against one of the vaccine ingredients.
4. Receiving immunosuppressive medication
5. Known or suspected immunological disorder
6. Known or suspected bleeding disorder

Date of first enrolment
01/01/2026

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Rijksinstituut voor Volksgezondheid en Milieu
PO Box 1
Bilthoven
Netherlands
3720 BA

Sponsor information

Organisation
National Institute for Public Health and the Environment

ROR
https://ror.org/01cesdt21

Funder(s)

Funder type

Government

Funder Name
Ministerie van Volksgezondheid, Welzijn en Sport

Alternative Name(s)
Dutch Ministry of Health, Welfare and Sport, VWS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date