ISRCTN61378987 https://doi.org/10.1186/ISRCTN61378987

# Measles, mumps and rubella vaccine given to 14 month old children, administered subcutaneously versus intramuscularly

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 02/05/2007 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 02/05/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 29/07/2008 | Infections and Infestations | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
LTR086a

# Study information

### Scientific Title

### Study objectives
Measles, Mumps and Rubella (MMR) vaccine administered intramuscularly induces the same adverse effects and immunogenicity as subcutaneously.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approval received from the TNO Preventie en Gezondheid (this committee ceased to exist as of 01-Jan-2004) on the 20th January 1999 (ref: METC 98/61).

### Study design
Non-randomised, interventional, parallel group trial

### Primary study design
Interventional

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Prevention

### Participant information sheet

### Health condition(s) or problem(s) studied
Measles Mumps Rubella (MMR) vaccination

### Interventions
Two groups of children aged 14 months:
1. MMR vaccine (RVG number 17654) given subcutaneously (n = 34)
2. MMR vaccine (RVG number 17654) given intramuscularly (n = 34)

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Measles, Mumps and Rubella (MMR) vaccine

### Primary outcome measure
The occurrence of adverse events after the MMR vaccine administered subcutaneously versus intramuscularly as recorded by the parents (non-blinded).

### Secondary outcome measures
The immunogenicity of the MMR vaccine administered subcutaneously versus intramuscularly as measured by the antibody titres before and 12 weeks after vaccination. Antibody titres are determined by a twofold serial dilution Enzyme Linked Immunosorbert Assay (ELISA).

### Overall study start date
01/02/1998

### Completion date
01/09/2001

## Eligibility

### Key inclusion criteria
1. Children aged 12 to 18 months
2. In good general health

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
12 Months

### Upper age limit
18 Months

### Sex
Not Specified

### Target number of participants
67

### Key exclusion criteria
1. Proven allergy for any of the vaccine components
2. Contraindication for MMR vaccination (e.g. administration of blood products within three months before MMR vaccination)
3. Known immune disorder
4. Coagulation disorder (not being able to receive intramuscular injection)
5. Parents/legal representatives who cannot participate optimally in the trial due to, e.g., language issues
6. Previous MMR vaccination
7. Administration of another vaccine simultaneous to the MMR vaccination

**Date of first enrolment**
01/02/1998

**Date of final enrolment**
01/09/2001

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**National Institute for Public Health and the Environment (RIVM)**
Bilthoven
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# Sponsor information

**Organisation**
National Institute of Public Health and Environmental Protection (RIVM) (The Netherlands)

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**Sponsor type**
Government

**Website**
http://www.rivm.nl/en/

**ROR**
https://ror.org/01cesdt21

# Funder(s)

**Funder type**
Government

**Funder Name**
The Netherlands Healthcare Inspectorate (The Netherlands)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Results | 26/10/2001 | | Yes | No |