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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