MMR vaccine given to 14 month old children, administered subcutaneously versus intramuscularly.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20165

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Infectious Diseases, Measles, Mumps, Rubella.

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM)
Source(s) of monetary or material Support: The Netherlands Healthcare Inspectorate

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The immunogenicity of the MMR vaccine administered subcutaneously versus intramuscularly as measured by the antibody titers before and 12 weeks after vaccination. Antibody titers are determined by a twofold serial dilution ELISA.

Study description

Background summary

In this study we compared the recommended subcutaneous administration of the RIVM MMR vaccine with the intramuscular administration for both safety and immunogenicity. Pain immediately after vaccination was the most reported adverse reaction. Serious pain was more often reported after subcutaneous vaccination. However, because of the low number of participants in this study, pain serves only as an indication since statistical backing is lacking. Both subcutaneous and intramuscular administered MMR vaccine induced a good immune response. In conclusion, inadvertent intramuscular administration of MMR vaccine is not enough reason for revaccination.

Study objective

MMR vaccine administered intramuscularly induces the same adverse effects and immunogenicity as subcutaneously.

Study design

N/A

Intervention

2 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).

Contacts

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Eligibility criteria

Inclusion criteria

1. Children aged 12 to 18 months in good general health.

Exclusion criteria

1. Proven allergy for any of the vaccine components;

2. Contraindication for MMR vaccination (e.g. administration of blood products within 3 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. laguage issues;

6. Previous MMR vaccination;

7. Administration of another vaccine simultaneous to the MMR vaccination.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-1998
Enrollment:	67
Type:	Actual

Ethics review

Positive opinion

Date:	02-04-2007
Application type:	First submission

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
NTR-new	NL919
NTR-old	NTR943

Register	ID
Other	: LTR086a
ISRCTN	ISRCTN61378987

Study results

Summary results

AB Lafeber et al. RIVM report 000002 001, sep. 2001