

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation and comparison of immunogenicity of the MMR vaccines used in Iranian National Vaccination Program in 12 month old infants, a non-randomized clinical trial

Protocol summary

Study aim

Evaluation and comparison of immunogenicity of the MMR vaccines used in Iranian National Vaccination Program in 12 month old infants

Design

This is a multi-center, non-randomized, and immunogenicity lab blinded clinical trial.

Settings and conduct

Study will be conducted in selected health centers of Iran and Shahid Beheshti University of Medical Sciences. Two heel capillary blood samples will be collected by Dried Blood Spot method on filter papers at the time of MMR vaccination and 6 weeks later.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 12 month old infants with normal growth and development attending health center for their first dose of MMR vaccination, parental consent. Exclusion criteria: Having medical conditions affecting child immunity such as congenital or acquired immunodeficiency, history of coagulation disorders or receiving blood products or immunoglobulins within the last three months and prior measles infection.

Intervention groups

Intervention group 1: Receiving Measles, Mumps, and Rubella (MMR) vaccine manufactured by the Razi Vaccine and Serum Research Institute. Intervention group 2: Receiving MMR vaccine manufactured by serum institute of India

Main outcome variables

Primary outcomes: Measles-specific IgG antibody response (Seroconversion rate), Change in serum level of measles-specific IgG antibodies 6 weeks after vaccination (Geometric Mean Fold Increase (GMFI)). Secondary outcomes: Non-inferiority of seroconversion rate of the Measles-specific IgG antibody in MMR vaccine manufactured by the Razi institute and serum institute of India compared with expected 85% at a margin of 10%

(Adequacy of measles-specific IgG antibody response), Rubella and Mump specific IgG antibody response (Seroconversion rate), Change in serum level of Rubella and Mumps specific IgG antibodies 6 weeks after vaccination (Geometric Mean Fold Increase (GMFI))

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049709N7**

Registration date: **2026-07-01, 1405/04/10**

Registration timing: **prospective**

Last update: **2026-07-01, 1405/04/10**

Update count: **0**

Registration date

2026-07-01, 1405/04/10

Registrant information

Name

Ali Eshaghi

Name of organization / entity

Razi Vaccine and Serum Research Institute

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-11, 1405/04/20

Expected recruitment end date

2027-01-10, 1405/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of immunogenicity of the MMR vaccines used in Iranian National Vaccination Program in 12 month old infants, a non-randomized clinical trial

Public title
Evaluation of immunogenicity of the MMR vaccines used in Iranian National Vaccination Program in 12 month old infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 12 month old infants attending health center for their first dose of MMR vaccination Signed written informed consent by parents or legal guardian Having normal weight and height according to developmental curves Living in the area covered by the Health center and no plans to move in the next 6 weeks
Exclusion criteria:
 History of receiving blood products or immunoglobulins within the last three months Having medical conditions affecting child immunity such as congenital or acquired immunodeficiency History of measles infection authenticated by a health professional Un-collaborative parents History of infertility or IVF in parents prior to conception of this child History of coagulation disorders in the child

Age
From **12 months** old to **12 months** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **420**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Immunogenicity will be assessed simultaneously for the two MMR vaccines currently used in the Iranian National Vaccination Program. All samples will be coded before being sent to the reference laboratory. Study statistician will also be unaware of the type of vaccine received by each participant.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees Of Razi Vaccine and Serum Research Institute

Street address

Razi Vaccine and Serum Research Institute, Shahid Beheshti Blvd., Hesarak, Karaj, Alborz Province, Iran.

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۳۱۹۷۵-۱۴۸

Approval date

2025-12-02, 1404/09/11

Ethics committee reference number

IR.RVSRI.REC.1404.004

Health conditions studied

1

Description of health condition studied

Measles

ICD-10 code

B05

ICD-10 code description

Measles

2

Description of health condition studied

Rubella

ICD-10 code

B06

ICD-10 code description

Rubella [German measles]

3

Description of health condition studied

Mumps

ICD-10 code

B26

ICD-10 code description

Mumps

Primary outcomes

1

Description

Measles-specific IgG antibody response (Seroconversion rate): In this outcome, we will measure the proportion of participants whose ELISA IgG antibody test results become positive after 6 weeks. This proportion will be calculated both with and without inclusion of borderline positive ELISA test results in the numerator.

Timepoint

Measurements will be done at the time of administration of the MMR vaccine (Day 0) and 6 weeks later.

Method of measurement

Capillary blood will be collected on filter papers using heel puncture and Dried Blood Spot method. Antibody measurements will be done by ELISA method at National Measles Surveillance center.

2

Description

Change in serum level of measles-specific IgG antibodies 6 weeks after vaccination (Geometric Mean Fold Increase (GMFI): Geometric mean concentration (GMC) of antibodies will be measured and compared at the time of vaccination and 6 weeks later.

Timepoint

Measurements will be done at the time of administration of the MMR vaccine (Day 0) and 6 weeks later.

Method of measurement

Capillary blood will be collected on filter papers using heel puncture and Dried Blood Spot method. Antibody measurements will be done by ELISA method at National Measles Surveillance center.

Secondary outcomes

1

Description

Adequacy of measles-specific IgG antibody response following the first dose of MMR vaccine manufactured by the Razi Vaccine and Serum Research Institute.

Timepoint

This outcome will be calculated at the end of the study

Method of measurement

Non-inferiority of seroconversion rate of the Measles-specific IgG antibody in MMR vaccine manufactured by the Razi institute will be assessed. Comparison will be made to the expected seroconversion rate of 85% at a margin of 10%

2

Description

Adequacy of measles-specific IgG antibody response following the first dose of MMR vaccine manufactured by the Serum Institute of India.

Timepoint

This outcome will be calculated at the end of the study

Method of measurement

Non-inferiority of seroconversion rate of the Measles-specific IgG antibody in MMR vaccine manufactured by the Serum Institute of India will be assessed. Comparison will be made to the expected seroconversion rate of 85% at a margin of 10%

3

Description

Rubella and Mump specific IgG antibody response (Seroconversion rate): In this outcome, we will measure the proportion of participants whose ELISA IgG antibody test results become positive after 6 weeks. This proportion will be calculated both with and without inclusion of borderline positive ELISA test results in the numerator.

Timepoint

Measurements will be done at the time of administration of the MMR vaccine (Day 0) and 6 weeks later.

Method of measurement

Capillary blood will be collected on filter papers using heel puncture and Dried Blood Spot method. Antibody measurements will be done by ELISA method at National Measles Surveillance center.

4

Description

Change in serum level of Rubella and Mumps specific IgG antibodies 6 weeks after vaccination (Geometric Mean Fold Increase (GMFI): Geometric mean concentration (GMC) of antibodies will be measured and compared at the time of vaccination and 6 weeks later.

Timepoint

Measurements will be done at the time of administration of the MMR vaccine (Day 0) and 6 weeks later.

Method of measurement

Capillary blood will be collected on filter papers using heel puncture and Dried Blood Spot method. Antibody measurements will be done by ELISA method at National Measles Surveillance center.

Intervention groups

1

Description

Intervention group 1: Infants in this group will receive the MMR vaccine (Mumps, Measles, and Rubella) manufactured by Razi vaccine and serum research institute. This vaccine is one of the vaccines used in the Iranian National Vaccination Program.

Category

Other

2

Description

Intervention group 2: Infants in this group will receive the MMR vaccine (Mumps, Measles, and Rubella) manufactured by serum institute of India. This vaccine is one of the vaccines used in the Iranian National

Vaccination Program.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Safdari

Full name of responsible person

Azade Safaee

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Name of recruitment center

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Name of recruitment center

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Name of recruitment center

Hesar Amir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Razi Vaccine and Serum Research Institute

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Razi Vaccine and Serum Research Institute

Full name of responsible person

Ladan Mokhberosafa

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Immunogenicity of MMR data

When the data will become available and for how long

A year after completion of study

To whom data/document is available

Academic institution

Under which criteria data/document could be used

A joint project should be defined and approved by Razi Vaccine and Serum Research Institute

From where data/document is obtainable

Please send your requests to Dr Ladan Mokhberosafa at lady.katbi@yahoo.com or l.mokhber@rvsri.ac.ir

What processes are involved for a request to access data/document

Any joint project needs approval from vice chancellor for research and RVSRI ethics committee

Comments

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