# 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

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**Province**

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**Postal code**

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 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 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 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 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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**Recruitment center**

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**Recruitment center**

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**Recruitment center**

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# Sponsors / Funding sources

## 1

**Sponsor**
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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**
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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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