Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country

Iran (Islamic Republic of)

Phone

+98 26 3457 0038

Email address

a.eshaghi@rvsri.ac.ir

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.

City

Tehran

Province

Tehran

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

Street address
No. 5, Opposite Water Organization, Nabard St., Pirouzi St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 3318 3536

Fax
+98 21 6674 4119

Email
azadesafaee@gmail.com

2

Recruitment center

Name of recruitment center
Afsarieh

Full name of responsible person
Azade Safaee

Street address
No. 3, 44th Street, 15-Metri Sevvom Street, Afsarieh, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 3315 7333

Fax
+98 21 6674 4119

Email
azadesafaee@gmail.com

3

Recruitment center

Name of recruitment center
Salavati

Full name of responsible person
Azade Safaee

Street address
No. 59, First Air Force St. (Nirou Havaei 1st St.), Pirouzi St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 7747 2287

Fax
+98 21 6674 4119

Email
azadesafaee@gmail.com

4

Recruitment center

Name of recruitment center
Hakimiyeh

Full name of responsible person
Azade Safaee

Street address
Behind Shahrvand Store, Farhang St., Bahar Blvd., Hakimiyeh, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 7730 6788

Email
azadesafaee@gmail.com

5

Recruitment center

Name of recruitment center
Haj Mobaraki

Full name of responsible person
Azade Safaee

Street address
Shahrezaei St., Farshadi St., Lavizan, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 2293 6644

Email
azadesafaee@gmail.com

6

Recruitment center

Name of recruitment center
Imam Hasan

Full name of responsible person
Azade Safaee

Street address
No. 4, Bani Hashem Alley, 137th St., 196th East St.,

Parvin Square, Tehranpars, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 7735 8711

Email
azadesafaee@gmail.com

7

Recruitment center

Name of recruitment center
Samarkandi

Full name of responsible person
Azade Safaee

Street address
No. 175, Ardibehesht Blvd., Between 206th and 212th Streets, Farjam St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 7737 6205

Email
azadesafaee@gmail.com

8

Recruitment center

Name of recruitment center
Hesar Amir

Full name of responsible person
Azade Safaee

Street address
Chahardeh Masoom Comprehensive Health Service Center, Niloufar 2 St., Shohada Blvd., Hesar Amir, Pakdasht, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 3640 2478

Email
azadesafaee@gmail.com

9

Recruitment center

Name of recruitment center
Imam Zaman (AJ) Comprehensive Health Service Center

Full name of responsible person
Azade Safaee

Street address
Corner of Mahdieh 30 St., Mohammadabad St., Qarchak, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 3643 0564

Email
azadesafaee@gmail.com

10

Recruitment center

Name of recruitment center
Madani Health Center

Full name of responsible person
Azade Safaee

Street address
Opposite Government Service Office, Rajaei Shomali St., Esfandabad Crossroad, Qarchak, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 3625 4177

Email
azadesafaee@gmail.com

11

Recruitment center

Name of recruitment center
Martyrs of Service Comprehensive Health Service Center

Full name of responsible person
Azade Safaee

Street address
Two-Story Building, Tarannom St., 9 Dey Blvd., Poinak, Qarchak, Tehran Province, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۳۳۶-۱۵۷۹۴

Phone
+98 21 3625 4177

Email
azadesafaee@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi Vaccine and Serum Research Institute
Full name of responsible person
Ali Eshaghi
Street address
Hesarak, Shahid Beheshti St.,
City
Karaj
Province
Alborz
Postal code
3197619751
Phone
+98 26 3405 0400
Fax
+98 26 3405 0400
Email
a.eshaghi@rvsri.ac.ir
Web page address
https://www.rvsri.acc.ir
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
Public Health/Community Medicine
Street address
Shahid Beheshti st.,
City
Karaj, Hesarak
Province
Alborz
Postal code
3197619751
Phone
+98 26 3405 0400 ext. 3039
Fax
+98 26 3405 0400
Email
lady.katbi@yahoo.com
Web page address
https://www.rvsri.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Masoud Solaymani-Dodaran
Position
Professor of Epidemiology
Latest degree
Specialist
Other areas of specialty/work
Epidemiology
Street address
Hemmat freeway, next to Milad tower
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4751
Fax
+98 21 8670 4751
Email
msdodran@gmail.com
Web page address
https://www.iums.ac.ir

Person responsible for updating data

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
Public Health/Community Medicine
Street address
Shahid Beheshti st.,
City
Karaj, Hesarak
Province
Alborz
Postal code

3197619751

Phone

+98 26 3405 0400

Fax

+98 26 3405 0400

Email

lady.katbi@yahoo.com

Web page address

https://www.rvsri.ac.ir

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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