

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Randomized double blind clinical trial (phase 2) RAZI- MMR vaccines in comparison with a standard vaccine in 12 - 24 months old children.

Protocol summary

Summary

This study is a double blind, randomized, controlled phase II clinical trial. The aims of this study are assessment of immunogenicity and safety of the measles, mumps, and rubella vaccine with new mumps component (RS12). Inclusion criteria include: no previous history of immunization against measles, mumps and rubella; no known exposure to measles, mumps and rubella in the preceding 4 weeks; not being treated for any condition that impairs the immune response and exclusion criteria include: fever of $>38^{\circ}\text{C}$ at the time of assessment other signs of acute infection, administration of immunoglobulin or blood transfusion within the previous 3 months and a history of allergy to any vaccine components. 420 Healthy children 12 to 24 months of age will be divided in two groups after meeting inclusion criteria and obtaining written informed consent from their parents. Children will be randomly assigned (1:1) to receive 2 dose of either MMR (RS12) or MMR used in routine vaccination, administered 0/5 cc subcutaneously, one dose will be injected in 12 months of age and second dose will be injected in 18 months of age. Blood samples will be obtained from each subject for immunogenicity analysis immediately before vaccination and 6-8 weeks after first vaccination and 6 weeks after second vaccination. For early adverse event, children will be observed during half hour (30 minutes) after each vaccination by physician and late adverse event will be recorded within the 6-8 weeks after each vaccination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206304412N6**

Registration date: **2012-07-30, 1391/05/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-30, 1391/05/09

Registrant information

Name

Saeedeh Forghani

Name of organization / entity

Razi Vaccine and Serum Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 26 1457 0039

Email address

s.forghani@rvsri.ir

Recruitment status

Recruitment complete

Funding source

Razi Vaccine and Serum Research Institute

Expected recruitment start date

2015-08-08, 1394/05/17

Expected recruitment end date

2016-08-08, 1395/05/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized double blind clinical trial (phase 2) RAZI- MMR vaccines in comparison with a standard vaccine in 12 - 24 months old children.

Public title

Immunogenicity and safety assessments of MMR vaccine with new mumpes component (RS12)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: in 12 - 24 months old children Negative history of any exposure to measles , rubella and mumps in the the preceding 4 weeks ; Negative history of previous MMR immunization ; Negative history of immunosuppressive therapy; Negative history of previous infection by measles , rubella and mumps viruses ; obtaining written informed consent ; Negative history of radiotherapy; Exclusion criteria : in 12 - 24 months old children Positive history of autoimmune disorders , genetic and congenital disease; Positive history of kidney and liver disease; fever of >38.cc at time of assessment; Positive history of other signs of acute infections; Positive history of administration immunoglobins or blood transfusions within the previous three months; Positive history of allergy to any vaccine components; Positive history of prematurity ,mental retardation ; Positive history of convulsion or any neurological disorder;

Age

From **1 year** old to **2 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **420**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iranian National Ethics Committee

Street address

Ministry of Health and Medical Education

City

Tehran

Postal code

Approval date

2011-11-19, 1390/08/28

Ethics committee reference number

48/1-ك90پ

Health conditions studied

1

Description of health condition studied

Measles

ICD-10 code

B05

ICD-10 code description

viral infections characterized by skin and mucous membrane lesions

2

Description of health condition studied

rubella

ICD-10 code

B06

ICD-10 code description

viral infections characterized by skin and mucous membrane lesions

3

Description of health condition studied

Mumps

ICD-10 code

B26

ICD-10 code description

Other viral diseases

Primary outcomes

1

Description

Antibody titer of mumps

Timepoint

Before first vaccination and 6-8 weeks after each vaccination

Method of measurement

Eliza test

2

Description

Antibody titer of rubella

Timepoint

Before first vaccination and 6-8 weeks after each vaccination

Method of measurement

Eliza test

3

Description

Antibody titer of measles

Timepoint

Before first vaccination and 6-8 weeks after each vaccination

Method of measurement

Eliza test

Secondary outcomes

1

Description

Allergic reaction

Timepoint

One hour after each vaccination

Method of measurement

Assessed by the physician

2

Description

Anaphylaxy

Timepoint

Half hour(30 minutes) after each vaccination

Method of measurement

Assessed by the physician

3

Description

Febrile convulsion

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

4

Description

Thrombocytopenia

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

5

Description

Encephalopathy

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

6

Description

Pain of injection site

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

7

Description

Swelling of injection site

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

8

Description

Redness of injection site

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

9

Description

Fever

Timepoint

Within 6-8 weeks after each vaccination

Method of measurement

Documented and assessed by the physician

Intervention groups

1

Description

Interventional group: MMR vaccine with new mumps component (RS12)

Category

Prevention

2

Description

MMR vaccine which is used in routine vaccination

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected medical centers in Tehran province(Iran university of medical sciences)

Full name of responsible person

Dr Mahmood Mirafzali

Street address

Hesarak, karaj

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi Vaccine & Serum Research Institute

Full name of responsible person

Dr. Hamid kohram

Street address

Razi Vaccine & Serum Research Institute, Hesarak ,
Karaj

City

Karaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Razi Vaccine & Serum Research Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Razi Vaccine & Serum Research Institute

Full name of responsible person

Seyed Mahmood Mirafzali

Position

MD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty