Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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◦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 in18 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 measeles , 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 measeles , 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

Ttehran

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 membraine lesions

2

Description of health condition studied

rubella

ICD-10 code

B06

ICD-10 code description

viral infections characterized by skin and mucous membraine 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 measeles

Timepoint

Before first vaccination and 6-8 weeks ater 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 qroup: 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 &Sserum Research Institute

Full name of responsible person

Seyed Mahmood Mirafzali

Position

MD

Other areas of specialty/work

Street address

Razi Vaccine & Serum Research Institute, Hesarak , karaj

City

Karaj

Postal code

3197619751

Phone

+98 263457003846

Fax

+98 26 3450 2852

Email

mirmir1347@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi Vaccine and Serum Research Institute

Full name of responsible person

Saeedeh Forghani

Position

MD

Other areas of specialty/work

Street address

Razi Vaccine and Serum Research Institute, Hesarak , Karaj

City

Karaj

Postal code

3197619751

Phone

+98 26457003846

Fax

+98 26 3450 2852

Email

s.forghani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Razi Vaccine & Serum Research Institute

Full name of responsible person

Saeedeh Forghani

Position

MD

Other areas of specialty/work

Street address

Razi Vaccine & Serum Research Institute, Hesarak , Karaj

City

Karaj

Postal code

3197619751

Phone

+98 26457003846

Fax

+98 26 3450 2852

Email

s.forghani@yahoo.com

Web page address

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