

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Clinical trial (phase 1) of RAZI- MMR vaccine in 18-49 years old volunteers

Protocol summary

Summary

In open label phase I clinical trial of this study, we are going to vaccinate 40 volunteers, who are 18-49 year-old. Informed consent will be obtained from all of the participants. Inclusion criteria for recruiting participants are: negative history of any contact with patients infected by Measles, Rubella or Mumps viruses during the last two months; not being under Immunocompromising treatment; not being pregnant and no plan for pregnancy within the next three months; not being under radiotherapy. Exclusion criteria for recruiting participants are: Positive history of Immunodeficiency; Positive history of Congenital disorders; Positive history of Genetic disease; positive history of Liver disease; positive history of Kidney disease; Temperature > 38.0 °C at the time of the first visit; presence of an acute febrile disease at the time of the first visit; Positive history of blood transfusion during the last three months; Positive history of receiving intramuscular immunoglobulin during the last three months; Positive history of severe adverse effect after previous MMR Vaccine injection; Positive history of egg hypersensitivity ; positive history of thrombocytopenia. Each volunteer will receive one dose of S12 MMR vaccine and we will withdraw 2 blood samples (one sample just before vaccination and one sample two weeks after) for hematology and biochemistry tests. In this study, all volunteers will be under close observation for one hour after vaccination and then they will be followed daily for two weeks, and weekly for four weeks to assess the possible side effects of vaccination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904284412N1**

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

Registration timing: **retrospective**

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@rsvri.ir

Recruitment status

Recruitment complete

Funding source

Razi Vaccine and Serum Research Institute

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial (phase 1) of RAZI- MMR vaccine in 18-49 years old volunteers

Public title

Safety study of RAZI- MMR vaccine in 18-49 years old volunteers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Negative history of any contact with patients infected by Measles, Rubella or Mumps viruses during the last two months; Not being under Immunocompromising treatment; Giving Informed Consent; Not being Pregnant and no plan for pregnancy within the next three months; Negative history of Autoimmune disorders; Not being under Radiotherapy; Negative history of any Chronic diseases. Exclusion Criteria: Positive history of Immunodeficiency; Positive history of Congenital disorders; Positive history of Genetic disease; Positive history of Liver disease; Positive history of Kidney disease; Temperature > 38.0 °C at the time of the first visit; Presence of an Acute Febrile disease at the time of the first visit; Positive history of blood transfusion during the last three months; Positive history of receiving intramuscular immunoglobulin during the last three months; Positive history of Hypersensitivity to Vaccine; Positive history of severe adverse effect after previous MMR Vaccine injection; Positive history of active tuberculosis; Positive history of egg hypersensitivity; Positive history of thrombocytopenia.

Age

From **18 years** old to **49 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Razi Vaccine and Serum Research Institute

Street address

Razi Vaccine and Serum Research Institute, Karak Hesarak

City

Karaj

Postal code

31975/148

Approval date

2010-03-07, 1388/12/16

Ethics committee reference number

1-18-18-8801

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**

Mumps

ICD-10 code

B26

ICD-10 code description

Mumps

3**Description of health condition studied**

Rubella

ICD-10 code

B06

ICD-10 code description

Rubella

Primary outcomes**1****Description**

Urea

Timepoint

Before vaccination and two weeks after vaccination

Method of measurement

Autoanalyzer- Biochemical reagent (mg/dl)

2**Description**

Blood cell count and differential count of white blood cell

Timepoint

Before vaccination and two weeks after vaccination

Method of measurement

cell counter

3**Description**

Creatinin

Timepoint

Before vaccination and two weeks after vaccination

Method of measurement

Autoanalyzer- Biochemical reagent (mg/dl)

4

Description

Liver enzymes

Timepoint

Before vaccination and two weeks after vaccination

Method of measurement

Autoanalyzer- Biochemical reagent (IU/ml)

5

Description

Anaphylaxy

Timepoint

Within One hour after vaccination

Method of measurement

Assessed by the physician

6

Description

Allergic reaction

Timepoint

Within one hour after vaccination

Method of measurement

Assessed by the physician

7

Description

Thrombocytopenia

Timepoint

Within 6 weeks after vaccination

Method of measurement

Cell counter

8

Description

Fever

Timepoint

Within 6 weeks after vaccination

Method of measurement

Documented and assessed by the physician

9

Description

Pain of the injection site

Timepoint

Within 6 weeks after vaccination

Method of measurement

Documented and assessed by the physician

10

Description

Swelling of the injection site

Timepoint

Within 6 weeks after vaccination

Method of measurement

Documented and assessed by the physician

11

Description

Redness of the injection site

Timepoint

Within 6 weeks after vaccination

Method of measurement

Documented and assessed by the physician

12

Description

Severe headache

Timepoint

Within 6 weeks after vaccination

Method of measurement

Documented and assessed by the physician

Secondary outcomes

empty

Intervention groups

1

Description

we will inject 0/5 cc MMR vaccine with new mumps component (RS12)

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Razi Vaccine and Serum Research Institute

Full name of responsible person

Gholamhosein Sabiri

Street address

Hesarak Karaj

City

Karaj

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Razi Vaccine and Serum Research Institute

Full name of responsible person

Abdolhosein Dalimi (Head of Institute)

Street address

PO box 31975/148 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 and 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 and Serum Research Institute

Full name of responsible person

Saeedeh Forghani

Position

Doctor of Medicine /Responsible of clinical trial and ethics in Razi Vaccine and Serum Research Ins

Other areas of specialty/work**Street address**

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Full name of responsible person

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Full name of responsible person

Gholamhosein Sabiri

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Email**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