

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of immunogenicity and short term reactogenicity of a local and a WHO approved commercial MMR vaccines in Iranian children and infants

Protocol summary

Summary

In this prospective study, 720 infants (one year old) and 720 children, aged 6 years old, were injected with MMR vaccine manufactured by Razi Institute of Iran or MMR vaccine approved by World Health Organization. Children received MMR vaccine at 12 and 18 months of age or 6 years of age, following the national vaccination schedule of Iran. In children, blood samples are collected before and 2 months after the vaccination and in infants blood is collected at 14, 18 and 20 months of age. The immunogenicity of the vaccines was assessed by ELISA using commercial kits. Reactogenicity was assessed by the physicians and parents for 2 months post-vaccination using diary cards.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806252471N1**

Registration date: **2010-06-14, 1389/03/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-06-14, 1389/03/24

Registrant information

Name

Saeed Zarei

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2020

Email address

szarei@avicenna.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of food and drugs, Ministry of Health and Medical Education, Secretariat of the 4th national economical, social and cultural development plan

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of immunogenicity and short term reactogenicity of a local and a WHO approved commercial MMR vaccines in Iranian children and infants

Public title

Comparison of immunogenicity and short term reactogenicity of MMR vaccine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy children Exclusion criteria: Incomplete vaccination card, immunodeficiency disease, severe asthma and allergy

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **720****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**

Avicenna Research Institute

Street address

Avicenna Research Institute, Shahid Beheshti University, Evin, Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Approval date

2008-07-09, 1387/04/19

Ethics committee reference number

2442/87

Health conditions studied**1****Description of health condition studied**

MMR

ICD-10 code

Z27.4

ICD-10 code description

Need for immunization against measles-mumps-rubella [MMR]

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

Antibody response against Measles, Mumps and Rubella

Timepoint

Start (0), 2, 6 month after vaccination

Method of measurement

ELISA

Secondary outcomes**1****Description**

vaccines reactogenicity

Timepoint

Immediately and two month after vaccination

Method of measurement

Checking by parents and physician

Intervention groups**1****Description**

Injecting WHO approved MMR vaccine (control group)

Category

Treatment - Drugs

2**Description**

Injecting Iranian MMR Vaccine (case group)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

East Health Center

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of food and drugs, Ministry of health and Medical Education

Full name of responsible person

Dr. Sheibani

Street address

Fakhrerazi st, Enghelab sq.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of food and drugs, Ministry of health and Medical Education

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**

Avicenna Research Institute

Full name of responsible person

Dr. Fazel Shokri

Position

PhD

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

Avicenna Research Institute, Shahid Beheshti University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Phone

+98 21 2243 2020

Fax

+98 21 2243 2021

Email

fazshok@yahoo.com

Web page address

University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Phone

+98 21 2243 2020

Fax

+98 21 2243 2021

Email

fazshok@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Avicenna Research Institute

Full name of responsible person

Dr. Saeed Zarei

Position

MD

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

Avicenna Research Institute, Shahid Beheshti University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Phone

+98 21 2243 2020

Fax

+98 21 2243 2021

Email

szarei@avicenna.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Avicenna Research Institute

Full name of responsible person

Dr. Fazel Shokri

Position

PhD

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

Avicenna Research Institute, Shahid Beheshti

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