Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 reactogencity 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 reactogencity
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
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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