

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of seroconversion rate of anti-measles antibody after vaccination with each measles vaccine strains which are in routine use in Iran (AIK-C and Edmonston-Zagreb) in 9 to 12 months infants of Zahedan District; a randomized controlled trial; Sistan-va-Baluchestan province of Iran; Fall 2015

Protocol summary

Summary

The main objective of this study was comparison of effectiveness of two kinds of anti-measles vaccines which are in routine use in immunization program of I.R.Iran. One of the vaccines is produced by Razi Institute of Serum and Vaccine Production and the other is Serum Institute of India. The first vaccine contains the AIK-C strain of measles vaccine and the other contains the Edmonston-Zagreb strain. Study population: Children 9 to 12 months of age resident in Zahedan, I.R.Iran. Inclusion criteria: The age of 9 to 12 months of age. Exclusion criteria: history of receiving measles containing vaccines and being a traveler to Zahedan. Sample size: total: 200 children. 100 in each arm. In four urban health centers the participants in the mentioned age range will be randomly allocated to one of the two arms of the study. In one arm the 'measles-rubella' (MR) vaccine produced by Razi Institute of Vaccine and Serum production and in the other arm MR vaccines produced by Serum institute of India will be administered. The cold chain and inoculation practices will be checked strictly. All the health workers in the study are well trained and educated. Supervision and quality control will be administered both in the district and in the provincial levels. Before vaccination and two months after vaccination serum samples will be taken from all participants. All lab tests will be performed in the National Reference Laboratory for Measles in Tehran University of Medical Sciences.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016032827144N1**

Registration date: **2016-05-10, 1395/02/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

Shahrokh Izadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5621 3729

Email address

izadish@yahoo.com

Recruitment status

Recruitment complete

Funding source

Centre for Communicable Diseases Control, Ministry of Health and Medical Education, I.R.Iran.

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

2016-05-28, 1395/03/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of seroconversion rate of anti-measles antibody after vaccination with each measles vaccine strains which are in routine use in Iran (AIK-C and Edmonston-Zagreb) in 9 to 12 months infants of Zahedan District; a randomized controlled trial; Sistan-va-Baluchestan province of Iran; Fall 2015

Public title

Measles-Rubella vaccination study.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: all children in the mentioned age range.
Exclusion criteria: positive history of inoculation of any kind of measles containing vaccine; being a temporary resident for the next 3 months in the region.

Age

From **9 months** old to **12 months** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Medical Research of Zahedan University of Medical Sciences

Street address

Pardis Daneshgah Olum Pezeshki, Dr Hesabi Square

City

Zahedan, Dr Hesabi Square, Pardis Daneshgah Olum Pezeshki

Postal code

9816743174

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

IR.ZAUMS.REC.1395.26

Health conditions studied

1

Description of health condition studied

Need for immunization against measles alone & Need for immunization against rubella alone

ICD-10 code

Z24.4 & Z2

ICD-10 code description

Need for immunization against measles alone & Need for immunization against rubella alone

Primary outcomes

1

Description

appearance of anti-measles antibodies 8 weeks after vaccination

Timepoint

8 weeks after vaccination

Method of measurement

measurement of antibody response using ELISA

Secondary outcomes

1

Description

appearance of anti-rubella antibodies

Timepoint

8 weeks after vaccination

Method of measurement

ELISA

Intervention groups

1

Description

The AIK-C group: This group will receive the measles-rubella vaccine produced by Razi Institute of Serum and Vaccine Production.

Category

Treatment - Other

2

Description

Edmonston-Zagreb group: In this group children will receive the measles-rubella vaccine produced by Serum Institute of India.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Balal Urban Health Centre

Full name of responsible person

Shahrokh Izadi

Street address

Shirabad

City

Zahedan

2**Recruitment center****Name of recruitment center**

Barazandeh the Martir Urban Health Centre

Full name of responsible person

Shahrokh Izadi

Street address

Karim-abad

City

Zahedan

3**Recruitment center****Name of recruitment center**

Hazrat Valiasr Urban Health Centre

Full name of responsible person

Shahrokh Izadi

Street address

End of Beheshti St.

City

Zahedan

4**Recruitment center****Name of recruitment center**

Hazrat Abolfazl Urban Health Centre

Full name of responsible person

Shahrokh Izadi

Street address

End of Shariati St.

City

Zahedan

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

Centre for Communicable Diseases Control, Ministry of Health and Medical Education

Full name of responsible person

Seyed Mohsen Zahraei

Street address

Nasr5 building, Falamak street, Shahrak Gharb

City

Tehran

Grant name

اولویت های پژوهشی

Grant code / Reference number

d304/13893; 17.11.2015

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

Yes

Title of funding source

Centre for Communicable Diseases Control, 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**

Health Promotion Research Centre, School of Public Health, Zahedan University of Medical Sciences

Full name of responsible person

Dr Shahrokh Izadi

Position

Faculty of School of Public Health/ MD; PhD

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

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izadish@yahoo.com

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

School of Public Health, Zahedan University of Medical Sciences,

Full name of responsible person

Shahrokh Izadi

Position

Faculty of School of Public Health/ MD; PhD

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

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Person responsible for updating data

Contact

Name of organization / entity

School of Public Health, Zahedan University of
Medical Sciences

Full name of responsible person

Shahrokh Izadi

Position

Faculty of School of Public Health/ MD; PhD

Other areas of specialty/work

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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