

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

comparison of pneumococcal serotypes separated from nasopharynx in children 6 months to 5 years old referred to before and after pneumococcal vaccination

Protocol summary

Summary

This non randomized quasi experimental trial was designed for evaluating the effect of pneumococcal conjugated Prevnar 13 vaccine on colonization of pneumococcus and type of serotypes. Fifty eight children with age of 6 months to 5 years without any serious diseases such as cardiac or pulmonary disease or diabetes, whom referred to pediatric clinics of Rasoul Akram Hospital, will participate to this trial after giving their parents an informed consent. All subjects will take a single dose from pneumococcal conjugated Prevnar 13. Vaccine intramuscular in their thigh or left Deltoid muscle by one educated person. One month before and 1 year after vaccination, we will take a sample from all participants' nasopharynx and investigate for colonization after 2 days culture. We also will determine type of serotypes before and one year after vaccination and will compare them together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012080510497N1**
Registration date: **2012-12-29, 1391/10/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-29, 1391/10/09

Registrant information

Name

Samileh Noorbakhsh

Name of organization / entity

Research Center of Pediatric Infectious

Diseases, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 6049

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of pneumococcal serotypes separated from nasopharynx in children 6 months to 5 years old referred to before and after pneumococcal vaccination

Public title

Effect of vaccination on nasopharyngeal pneumococcus serotype

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All children with age of 6 months to 5 years referred to pediatric clinics of Rasoul Akram Hospital after filling the consent letter by their patents.
Exclusion criteria: Previous disease including diabetes, spina bifida, asplenia, sickle cell anemia, innate or

acquired immune system deficiency, previous cochlear implantation, chronic cardiac and pulmonary disease.

Age

From **1 year** old to **5 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **58**

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 Tehran University of Medical Sciences

Street address

Research Center for Pediatric Infectious Diseases, 4th floor of Rasoul Akram Hospital, Niayesh St, Sattarkhan Ave

City

Tehran

Postal code**Approval date**

2012-02-08, 1390/11/19

Ethics committee reference number

90-12-101

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

Pneumonia due to Streptococcus pneumoniae

ICD-10 code

J13

ICD-10 code description

Pneumonia (acute) (double) (migratory) (purulent) (septic) (unresolved) - in (due to) - Streptococcus - pneumoniae

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

Colonization of organism

Timepoint

On month before and one year after injection of Prevna vaccine

Method of measurement

Culture

Secondary outcomes

empty

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

Injection of one dose (0.5 ml) Prevna 13 Produced by Pfizer company intramuscular (thigh in infants or upper arm in children). Comparing the pharyngeal colonization of pneumococcus before and after vaccination.

Category

Prevention

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

Rasoul Akram Hospital

Full name of responsible person

Samileh Noorbakhsh

Street address

Research Center for Pediatric Infectious Diseases, 4th floor of Rasoul Akram Hospital, Niayesh St, Sattarkhan Ave

City

Tehran

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

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

4th floor, Main Building of Tehran University of Medical sciences, Ghods St., Keshavarz Blvd.

City

Tehran

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

organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of
Medical Sciences

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**

Research Center for Pediatric Infectious Diseases

Full name of responsible person

Samileh Noorbakhsh

Position

Head of Centre

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

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Samileh Noorbakhsh

Position

Specialist in pediatric infectious, MD

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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