

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of specific-antibody formation in response to pneumococcal vaccination in children with systemic lupus erythematosus, and asthmatic control group, at Shiraz Namazi hospital and Imam Reza clinic

Protocol summary

Summary

In the present paper immunogenicity and safety of pneumococcal vaccine using SLEDAI and also humeral immunity function from the standpoint of specific antibody formation against polysaccharides antigens in children with Systemic Lupus Erythematosus are studied. In this study thirty children (range: 2 to 18 years old) with Systemic Lupus Erythematosus were participated as the case group, and thirty age and sex matched asthmatic children were participated as control group. The participants were selected by convenience sampling method. Exclusion criteria were fever, recent immunization, history of previous pneumococcal vaccination, history of hypersensitivity reaction to vaccination, platelet level less than 50,000 , mixed connective tissue disorders and IVIG injection in last 3 months. Thirty age and sex matched asthmatic controls were selected from children who attended out-patient clinic of asthma .It should be mentioned that controls were selected from mild asthmatic patients, and the patients with persistent or severe asthma and those with history of immunosuppressive therapy or PO corticosteroid consumption and those who has history of other immunodeficiency disorders were excluded from the control group. Informed consent was obtained from all participants or their parents. Before vaccination 5 cc venous blood sample was taken from both case and control group, then each participant received 0.5 ml intradeltoid injection of 23-valent pneumococcal vaccine . At least 3 weeks after vaccination, the patients (both groups) were visited at immunology clinic and 5cc venous blood sampling was done again. Both pre-vaccination and post-vaccination serum samples of all participants were sent to Allergy Research Center of Shiraz and anti-pneumococcal specific IgG titer was measured using enzyme linked immunoassay (ELISA).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811293361N1**

Registration date: **2013-11-26, 1392/09/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-26, 1392/09/05

Registrant information

Name

Soheila Alyasin

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of specific-antibody formation in response to pneumococcal vaccination in children with systemic lupus erythematosus, and asthmatic control group, at Shiraz Namazi hospital and Imam Reza clinic

Public title

immunogenicity of pneumococcal vaccine in children with systemic lupus erythematosus

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria of case group: 2-18 years old; SLE disease exclusion criteria of case group: fever; recent immunization; history of previous pneumococcal vaccination; history of hypersensitivity reaction to vaccination; platelet level less than 50,000 ; mixed connective tissue disorders; IVIG injection in last 3 months. inclusion criteria of control group: 2-18 years old; mild asthma exclusion criteria of control group: fever; recent immunization; history of previous pneumococcal vaccination; history of hypersensitivity reaction to vaccination; platelet level less than 50,000 ; mixed connective tissue disorders; IVIG injection in last 3 months; patients with persistent or severe asthma; patients with history of immunosuppressive therapy or PO corticosteroid consumption; patient with history of other immunodeficiency disorders

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

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

Shiraz University of Medical Science

Street address

Research department, Shiraz University of Medical Science, Shiraz, Fars.

City

Shiraz

Postal code

Approval date

2012-02-09, 1390/11/20

Ethics committee reference number

CT-P-90-2963

Health conditions studied

1

Description of health condition studied

systemic lupus erythematosus (SLE)

ICD-10 code

M32

ICD-10 code description

Systemic lupus erythematosus

Primary outcomes

1

Description

specific anti-pneumococcal antibody

Timepoint

before vaccination and 3 weeks after intervention

Method of measurement

using enzyme linked immunoassay kit specific for pneumococcal vaccine (ELISA)

2

Description

lupus activity

Timepoint

before vaccination and 3 weeks after intervention

Method of measurement

according to SLE disease activity index (SLEDAI)

Secondary outcomes

1

Description

SLE activity

Timepoint

before vaccination and 3 weeks after intervention

Method of measurement

according to SLE disease activity index

Intervention groups

1

Description

patients with SLE as case group were referred to Imam

Reza immunology clinic and at baseline a complete history-taking and physical examination was done. Informed consent was obtained from all participants or their parents. Before vaccination 5 cc venous blood sample was taken and then each participant received 0.5 ml intradeltoid injection of 23-valent pneumococcal vaccine (pneumovax-23; Sanofi Pasteur MSD). After vaccinations patients were observed at clinic for 30 minute by rheumatologist and adverse effects such as severe local swelling and redness, fever or weakness were recorded. At least 3 weeks after vaccination, the patients were visited at immunology clinic again and history-taking, physical exam and disease activity scoring was done again and their post-vaccination lab data were recorded in their questionnaires. Then again 5cc venous blood sampling was done. Both pre-vaccination and post-vaccination serum samples of all participants were sent to Allergy research center of Shiraz and anti-pneumococcal specific IgG titer was measured using ELISA. Antibody (IgG) response were analyzed with enzyme linked immunoassay kit specific for pneumococcal vaccine .

Category

Prevention

2**Description**

patients with asthma as control group were referred to Imam Reza immunology clinic. Informed consent was obtained from all participants or their parents. Before vaccination 5 cc venous blood sample was taken and then each participant received 0.5 ml intradeltoid injection of 23-valent pneumococcal vaccine (pneumovax-23; Sanofi Pasteur MSD). After vaccinations patients were observed at clinic for 30 minute by rheumatologist and adverse effects such as severe local swelling and redness, fever or weakness were recorded. At least 3 weeks after vaccination, the patients were visited at immunology clinic and 5cc venous blood sampling was done again. Both pre-vaccination and post-vaccination serum samples of all participants were sent to Allergy research center of Shiraz and anti-pneumococcal specific IgG titer was measured using ELISA. Antibody (IgG) response were analyzed with enzyme linked immunoassay kit specific for pneumococcal vaccine .

Category

Prevention

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

Namazee Hospital of Shiraz

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

Shiraz

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

Imam Reza Clinic of Shiraz

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

Shiraz

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

Shiraz University of Medical Science

Full name of responsible person

Gholamreza Hatam

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Research department, Shiraz University of Medical Science, Shiraz, Fars.

City

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

Yes

Title of funding source

Shiraz University of Medical Science

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**

Shiraz University of Medical Science

Full name of responsible person

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Position

Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist

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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