

# 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

Shiraz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4298

##### Email address

alyasins@sums.ac.ir

##### 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

**Street address**

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

**City**

Shiraz

**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**

Dr. Soheila Alyasin

**Position**

Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist

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

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Science

**Full name of responsible person**

Dr.Soheila Alyasin

**Position**

Associate Professor of Pediatrics, Pediatric Immunology and Allergy specialist

**Other areas of specialty/work**

**Street address**

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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*