

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The comparison of anti-pneumococcal antibody titer in pneumococcal conjugate 13 valent with polysaccharide 23 valent vaccination versus pneumococcal polysaccharide 23 valent vaccination alone in hemodialysis patients

#### Protocol summary

##### Study aim

The comparison of anti-pneumococcal antibody titer in pneumococcal conjugate 13 valent with polysaccharide 23 valent vaccination versus pneumococcal polysaccharide 23 valent vaccination alone in hemodialysis patients

##### Design

All patients who have been started hemodialysis at least 3 months and dialysed at least three times a week. In this study, randomized allocation of hemodialysis patients to two groups of conjugate 13 valent with polysaccharide 23 valent vaccination and polysaccharide 23 valent vaccination alone using Balanced Block randomization technique

##### Settings and conduct

Hemodialysis patients referring to Loghman Hospital Dialysis Center and Dr. Zahed Dialysis Center

##### Participants/Inclusion and exclusion criteria

All patients at least 16 years of age who have been started hemodialysis at least 3 months and dialysed at least three times a week. Patients will be excluded from the study if they have one of the following conditions: • immunocompromised • use immunosuppressive agents • Spleen function impairment • HIV infection • Malignancies • (bone marrow transplantation) • history of previous injection of pneumococcal vaccine

##### Intervention groups

This study is an experimental study in which the effect of antipneumococcal vaccine as an independent variable on the anti-pneumococcal antibody titers in the two groups of conjugate 13 valent with polysaccharide 23 valent vaccination and polysaccharide 23 valent vaccination alone of hemodialysis patients as a dependent variable will be investigated.

##### Main outcome variables

albumin level; KT / V calculation; serum hematocrit; anti-

pneumococcal antibody titer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171224038046N1**

Registration date: **2018-04-05, 1397/01/16**

Registration timing: **retrospective**

Last update: **2018-04-05, 1397/01/16**

Update count: **0**

##### Registration date

2018-04-05, 1397/01/16

##### Registrant information

##### Name

Sasan Tavana

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8825 6512

##### Email address

sasan.tavana2@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-02-19, 1396/11/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of anti-pneumococcal antibody titer in pneumococcal conjugate 13 valent with polysaccharide 23 valent vaccination versus pneumococcal polysaccharide 23 valent vaccination alone in hemodialysis patients

**Public title**

The Comparison of the efficacy of once injection of pneumococcal vaccination versus two times injection in hemodialysis patients

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients who have been started hemodialysis at least 3 months All patients who have been dialysed at least three times a week All patients who have at least 16 years old

**Exclusion criteria:**

Immunocompromised use immunosuppressive agents Spleen function impairment HIV infection Malignancies bone marrow transplantation history of previous injection of pneumococcal vaccine

**Age**

From **16 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Investigator

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The main researcher of the project is not informed about the allocation of the groups, so that the vaccines are provided to clinical care and divided into two groups based on the randomization of the participants in the project. Clinical care is aware of the allocation of the groups for following up the side effects. The participants in the plan will be informed which group is located in.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University of Medical Sciences, koodakyar street, Daneshjoo Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2017-11-22, 1396/09/01

**Ethics committee reference number**

IR-SBMU.SMSP.IRC.1396.572

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

Pneumonia

**ICD-10 code**

N18.6

**ICD-10 code description**

End stage renal disease

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

anti-pneumococcal antibody titer

**Timepoint**

1 month and 6 months after vaccination

**Method of measurement**

Human Anti-S. Pneumococcal vaccine (Pneumovax/CPS23) IgG ELISA Kit; (23 serotypes: 1, 2, 3, 4, 5, 6b, 7F, 8,9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F), quantitative

**Secondary outcomes****1****Description**

Evaluation of anti-pneumococcal antibody titre constancy

**Timepoint**

One month and six months after the date of the 23 valent polysaccharide vaccination

**Method of measurement**

To determine the antibody titer and ELISA test, The antibody titre will be measured with a specific kit (Copper Serum / Plasma)

## Intervention groups

### 1

#### Description

Intervention group: 25 patients received 13 valent anti pneumococcal vaccine, after 8 weeks received 23 valent vaccine.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 25 patients receive 23 valent vaccine.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Loghman hospital

##### Full name of responsible person

Zahra Ghanbari

##### Street address

Lashgar intersection, Makhsoos Street, Loghman Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1333631151

##### Phone

+98 21 5541 9423

##### Email

loghman.hospital@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research deputy of Shahid Beheshti Medical Science

##### Full name of responsible person

Dr. Seyyed Ali Ziayi

##### Street address

Shahid Beheshti University of Medical Sciences, koodakyar street, Daneshjoo Blvd.

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Tehran

##### Province

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##### Postal code

1983969411

##### Phone

+98 21 2243 1920

##### Email

pr.office@mail.sbu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research deputy of Shahid Beheshti Medical Science

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Shima Shahi

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

Shahid Modarres Hospital, Kaj Sqaure, Sa'adat Aabad St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2207 4101

##### Email

modarres@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Shima Shahi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Shima Shahi

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available