

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.

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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

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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

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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

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

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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