# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effects of Pegylated Filgrastim (PEG-G-CSF) Adjuvant on Improving Response to Hepatitis B Vaccine and HBs-Ab Serum Levels in Non-responder Chronic Hemodialysis Patients- A Randomized Double-Blind Clinical Trial

## Protocol summary


**Study aim**

1) Determining the HBs-Ab serum levels and improving the response rate to the hepatitis B vaccine in hemodialysis patients receiving PEG-G-CSF adjuvant 2) Determining the improved response rate to the hepatitis B vaccine in hemodialysis patients receiving PEG-G-CSF adjuvant by age, sex, and underlying diseases

**Design**

A controlled, double-blind, randomized, phase 2 clinical trial will be conducted on 80 hemodialysis patients. The block randomization method and SAS 9.3 software will be used for randomization.

**Settings and conduct**

All hemodialysis centers affiliated with SUMS will participate in this trial. Participants, outcome assessors, and statisticians will be blinded to treatment allocation. Randomization will be computer-generated by an independent data administrator.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age range between 18-70 years Dialysis adequacy 3 times a week Negative serology for HBsAg, total anti-HBC, anti HCV, HIV Receiving 3 IM doses of HBV vaccination and HBS-Ab titer <10 IU/L (non-responder patients) Exclusion criteria: Positive serology for HBsAg, total anti-HBC, anti HCV, HIV Prior use of any immunomodulatory agents like steroids/vaccine adjuvants and blood transfusion in last 6 months Scheduled to have kidney transplantation within 3 months

**Intervention groups**

Non-responder Hemodialysis patients will be randomized in a 1:1 ratio into 2 groups: Control Group received three booster dose of HBV vaccine IM (0, 2nd, 6th months), Adjuvant Group received a dose 6 mg/0.6 mL subcutaneous PEG-G-CSF (PegaGen®, CinnaGen) 24 hours before first booster dose of HBV vaccine IM, and received other two booster dose in the 2nd and 6th months. HBS-Ab was measured 1 month after the last two boosters (3rd, 7th months).

**Main outcome variables**

Antibody to hepatitis B surface antigen Response rates to vaccine Total leukocyte and neutrophile count


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20090701002113N4**
Registration date: **2025-12-19, 1404/09/28**
Registration timing: **prospective**

Last update: **2025-12-19, 1404/09/28**
Update count: **0**

**Registration date**

2025-12-19, 1404/09/28

**Registrant information**


**Name**

Jamshid Roozbeh

**Name of organization / entity**

Shiraz university of medical sciences

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-12-31, 1404/10/10
**Expected recruitment end date**
2026-08-01, 1405/05/10
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effects of Pegylated Filgrastim (PEG-G-CSF) Adjuvant on Improving Response to Hepatitis B Vaccine and HBs-Ab Serum Levels in Non-responder Chronic Hemodialysis Patients- A Randomized Double-Blind Clinical Trial

**Public title**
PEG-G-CSF in Non-responder Hemodialysis Patients HBs-Vaccination
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age range between 18 and 70 years Patients with dialysis adequacy 3 times a week Patients with negative serology for HBsAg, total anti-HBC, anti HCV, HIV 1 and 2 Receiving 3 IM doses of HBV vaccination and HBS-Ab titer <10 IU/L (non-responder patients) Patients of chronic renal failure with serum creatinine >2.0 mg/dL, Glomerular filtration rate (GFR) <60 mL/min on hemodialysis (HD)
**Exclusion criteria:**
Patients with positive serology for HBsAg, total anti-HBC, anti HCV, HIV 1 and 2 Prior use of any immunomodulatory agents like steroids/vaccine adjuvants in last 6 months Receiving blood transfusion in previous 6 months Scheduled to have kidney transplantation within 3 months History of active cancer or active infection under treatment Pregnancy, childbearing potential during the study period, or breastfeeding
**Age**
From **18 years** old to **70 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization will be performed by an independent statistician using a computerized random number generator via the SAS 9.3 software block randomization method (SAS Institute, Cary, NC, USA). Eligible participants will be randomly assigned 1:1 to a control group or a treatment group. All individuals who meet the inclusion/exclusion criteria at the first visit will be assigned to a group using the blocked randomization method, based on the allocation codes. Each patient will be assigned a unique study number. An independent data administrator who is not involved in clinical practice or patient recruitment will generate the randomization sequence.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, a double-blind design will be implemented. Participants, researchers, outcome assessors, and statisticians will remain unaware of the treatment allocation to prevent any bias resulting from expectations or preconceived notions. To ensure this, randomization lists will be generated by an independent data manager who is not involved in the study, using a computerized system. After generation, these lists will remain concealed from the researchers and other study team members and will be kept strictly confidential. Treatment allocation to participants will be done automatically by the software in a centralized manner, without human intervention. As a result, none of the researchers or outcome assessors will have knowledge of the treatment assigned to the participants throughout the study, and this process will remain confidential until the final analysis and result reporting.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of School of Medicine - Shiraz University of Medical Sciences
**Street address**
7th floor, University Central Building, Zand street
**City**
Shiraz
**Province**
Fars
**Postal code**
7134814336
**Approval date**
2024-06-16, 1403/03/27
**Ethics committee reference number**
IR.SUMS.MED.REC.1403.176

## Health conditions studied

### 1

**Description of health condition studied**
End-stage Kidney disease
**ICD-10 code**
N18.6
**ICD-10 code description**
End stage renal disease

## Primary outcomes

### 1

**Description**
HBs-Ab serum levels
**Timepoint**
Before first vaccin booster and one month after the last two vaccine boosters (3rd, 7th months)
**Method of measurement**
HBs-Ab serum levels will be measured by ELISA methods. 5 ml of blood will be collected in K2-EDTA tubes and HBs-Ab will be measured before PEG-G-CSF and the first vaccine booster injection, and 1 month after the last two boosters.

### 2

**Description**
Response rate to hepatitis B vaccine
**Timepoint**
One month after the third booster dose (month 7 of the study period)
**Method of measurement**
Calculating the percentage change from baseline antibody levels

## Secondary outcomes

### 1

**Description**
Total leukocyte count
**Timepoint**
One month after the third booster dose (month 7 of the study period)
**Method of measurement**
Performing CBC Diff test for patients

### 2

**Description**
Neutrophil count
**Timepoint**
One month after the third booster dose (month 7 of the study period)
**Method of measurement**
Performing CBC Diff test for patients

## Intervention groups

### 1

**Description**
Intervention group: will receive a dose of 6 mg/0.6 mL subcutaneous PEG-G-CSF 24 hours before the first booster dose of HBV vaccine IM, and receive the other two booster doses in the 2nd and 6th months.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: will receive three booster dose of HBV vaccine IM (0, 2nd, 6th months)
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Namazi Teaching Hospital
**Full name of responsible person**
Jamshid Roozbeh
**Street address**
Namazi Square, Zand Street
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**Province**
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### 2

**Recruitment center**
**Name of recruitment center**
Shahid Faghihi Hospital
**Full name of responsible person**
Ramin Radmehr
**Street address**
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hamid Mohammadi

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**Email**

vcrdep@sums.ac.ir

**Web page address**

https://research.sums.ac.ir/office

**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 Sciences

**Proportion provided by this source**

30

**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

### 2

**Sponsor**

**Name of organization / entity**

CinnaGen

**Full name of responsible person**

Mehdi Ahmadi

**Street address**

No. 34, Sepehr Street, Farahzadi Boulevard, West Town

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**Postal code**

3165933155

**Phone**

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**Email**

info@cinnagen.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

CinnaGen

**Proportion provided by this source**

70

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Industry

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Masjedi

**Position**

Professor of Nephrology

**Latest degree**

Specialist

**Other areas of specialty/work**

Nephrology

**Street address**

6th floor, Nephro-Urology Research Center, Research Tower, Khalili Street

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Masjedi

**Position**

Assistant Professor

**Latest degree**
Ph.D.
**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Jahrom University of Medical Sciences
**Full name of responsible person**
Sara Rahmanian
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
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srahmanian59@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All data is potentially shareable after de-identifying individuals.
**When the data will become available and for how long**
Access period starts 6 months after results are published.
**To whom data/document is available**
Only for researchers working in academic and scientific institutions.
**Under which criteria data/document could be used**
Reporting data based on our analyses in the form of books, reviews, and meta-analyses.
**From where data/document is obtainable**
Contact us with the following email: masjedi_f@sums.ac.ir
**What processes are involved for a request to access data/document**
Maximum two weeks after email sending and sufficient explanation of how the data will be used.
**Comments**