Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 71 1235 6400

Email address

roozbehj@sums.ac.ir

Recruitment status

recruiting

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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Fars
Postal code
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Phone
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+98 71 3647 4326
Email
nemazee_inf@sums.ac.ir
Web page address
https://namazi.sums.ac.ir

2

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Ramin Radmehr
Street address
Karim Khan Zand Street
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Email

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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

Street address

7th Floor, SUMS Central Biulding, Karim Khan Zand Street

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Phone

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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

City

Shiraz

Province

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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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roozbehj@hotmail.com

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
Physiology
Street address
6th floor, Nephro-Urology Research Center, Research Tower, Khalili Street
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Person responsible for updating data

Contact
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Full name of responsible person
Sara Rahmanian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Nephrology
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Jahrom
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Fars
Postal code
۴۶۱۹۹۷۴۱۴۸
Phone
0098 71 5330505
Email
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