

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The evaluation of effectiveness of dT vaccine on immune response to HB vaccine in non responder dialysis patients

#### Protocol summary

##### Summary

There are different strategies to improve immune response to HBV vaccine. One of them is to use different adjuvant such as GMCSF or tetanus vaccine. The aim of this study is to evaluate the effectiveness of dT vaccine on HBS Ab level in non-responder dialysis patients while being given simultaneously HBV vaccine. We initiated the study in Mar. 2009. 62 (hemo and peritoneal) dialysis patients who passed at least 3 dose HBV vaccination schedule and had HBS Ab less than 10, were traced for one year. The patients were divided into two groups, A (32 patients) and B (30 patients). Both of them received 3 dosees of HBV vaccine (40 µgr) intramuscularly into their left deltoid-muscle at 0, 1 and 6 months, but group B received dT vaccine into right deltoid-muscle simultaneously as well as first dose of HBV vaccine. We will test HBS Ab with ELISA method with Dia plus kits, 1-2m and 6m after completing vaccination. We hope our study will come to an end in August 2010

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138812093454N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-04-24, 1389/02/04

##### Registrant information

##### Name

Nasrin Namdari Ghareghani

##### Name of organization / entity

Isfahan Medical University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1651 0129

##### Email address

n\_namdari@resident.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University Of Medical Science ,Vice Chancellor For Research

##### Expected recruitment start date

2009-03-15, 1387/12/25

##### Expected recruitment end date

2010-08-06, 1389/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of effectiveness of dT vaccine on immune response to HB vaccine in non responder dialysis patients

##### Public title

The evaluation of effectiveness of dT vaccine on immune response to HB vaccine in non responder dialysis patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion:1)age>=18yr,2)hemodialysis and peritoneal dialysis patients,3)completed at least 3 dose HBV vaccine schedule and had HBS Ab <10 Exclusion:1)no compliance,2)renal transplant

##### Age

From **18 years** old to **149 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 50

**Randomization (investigator's opinion)**

Not randomized

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

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Isfahan Medical University

**Street address**

Isfahan

**City**

Isfahan

**Postal code****Approval date**

2009-03-01, 1387/12/11

**Ethics committee reference number**

388030

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

End Stage Renal Disease

**ICD-10 code**

N18.0

**ICD-10 code description**

ESRD

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

HBS Ab titer

**Timepoint**

1-2 m and 6 month after completing vaccination

**Method of measurement**

ELISA

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

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**Timepoint**

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**Method of measurement**

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**Intervention groups****1****Description**

dT vaccine injection simultaneously with first dose of HBV vaccine

**Category**

Treatment - Drugs

**2****Description**

HBV vaccine (40µgr) injection at 0,1,6 month

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

1)Hemodialysis Unit,Khorshid Hospital

**Full name of responsible person****Street address**

Isfahan

**City**

Isfahan

**2****Recruitment center****Name of recruitment center**

Hemodialysis Unit,Alzahra Hospital

**Full name of responsible person****Street address**

Isfahan

**City**

Isfahan

**3****Recruitment center****Name of recruitment center**

Hemodialysis Unit,shareati Hospital

**Full name of responsible person****Street address**

Isfahan

**City**  
Isfahan

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##### **Recruitment center**

**Name of recruitment center**  
Hemodialysis Unit, Saee Hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Khomeini Shahr

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##### **Recruitment center**

**Name of recruitment center**  
Hemodialysis Unit, Emam Khomeini Hospital  
**Full name of responsible person**  
**Street address**  
Isfahan  
**City**  
Falavarjan

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

**Name of organization / entity**  
Isfahan University Of Medical Science  
**Full name of responsible person**  
Vice Chancellor For Research  
**Street address**  
Isfahan  
**City**  
Isfahan  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Isfahan 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**  
Isfahan University Of Medical Sciences  
**Full name of responsible person**

Dr. Shahrzad Shahidi

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Assistant Prof. Nephrology  
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## **Person responsible for scientific inquiries**

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## **Person responsible for updating data**

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**Web page address**

## **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*