Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity

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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)comleted 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

Timepoint

Method of measurement

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

4

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

5

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

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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