Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy between intramuscular and intradermal injection of Hepatitis B vaccine in Buali Sina dialysis centre, Qazvin.

Protocol summary

Summary

The objective of the present randomized study is to compare the efficacy of low dose intradermal to conventional doses of intramuscular injection of hepatitis B vaccine in end stage renal failure patients. A total of 40 patients will be entered in this study. Inclusion criteria are over the age of 14, Anti HBS Ab titre below 10 U/ml and history of at least a course of vaccination against Hepatitis B. Exclusion criteria are malignant diseases, kidney transplantation and any cause of immunodeficiency such as AIDS. This patients randomly divided in 2 groups, in one group 4 intramuscular injections of 40µg of Euvax B (in mounts 0, 1, 2 and 6 totally 160 µg) and in other group intradermal injection of 2.5 µg of Euvax B in 2 different sites(totally 5µg) every 2 weeks to 2 mounts and then mountly to end of mount 4 and one injection in the sixth mount (totally 40 µg)will be injected. In all patients Anti HIV and Anti HCV will be measured and history of intravenous drug addiction, injection of blood products, duration of CRF, and type of dialysis will be recorded. The antibody titer (primary outcome) is measured in 2 groups at the end of 1, 6 and 12 mounts after end of the course of vaccination. In this study anti-HBs antibody level over 10 U/ml is considered protective.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805122276N1**
Registration date: **2009-12-05, 1388/09/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-12-05, 1388/09/14

Registrant information

Name

Behzad Bijani

Name of organization / entity

Qazvin University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1335 4808

Email address

bbijani@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Qazvin University of Medical Sciences

Expected recruitment start date

2008-09-06, 1387/06/16

Expected recruitment end date

2010-03-06, 1388/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy between intramuscular and intradermal injection of Hepatitis B vaccine in Buali Sina dialysis centre, Qazvin.

Public title

Comparison of efficacy between intramuscular and intradermal injection of Hepatitis B vaccine in Buali Sina dialysis centre, Qazvin.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: CRF patients who are under dialysis

(hemodyalisis or peritoneal dialysis) in Bualisina dialysis centre, HBsAg lower than 10 U/ml and at least a previous course of hepatitis B vaccination. Exclusion criteria: Presence of malignancy, severe malnutrition, positive HBsAg, kidney transplantation, immunocompromising disease such as AIDS.

Age
From **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Shaheed Bahonar Boulevard, Qazvin

City
Qazvin

Postal code

Approval date
2008-04-13, 1387/01/25

Ethics committee reference number
28/20/222

Health conditions studied

1

Description of health condition studied
End-stage renal disease

ICD-10 code
N18.0

ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
anti HBs antibody titre

Timepoint
Before intervention, 7, 12, and 18 months after intervention

Method of measurement
anti HBs antibody titre measurement

Secondary outcomes

empty

Intervention groups

1

Description
Recombinant Hepatitis B vaccine (Euvax B®) 2.5 µg at 2 different sites (totally 5µg) every 2 weeks untill 2 months and then monthly until end of the forth month and one injection at the sixth month (40 µg total dose) by intradermal injection.

Category
Prevention

2

Description
Recombinant Hepatitis B vaccine (Euvax B®) 40 µg at months: 0-1-2-6 (160 µg total dose) by intramuscular injection.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Buali Sina Hospital

Full name of responsible person
Behzad Bijani

Street address
Buali Sina Hospital

City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr.Saeed Asefzadeh,

Street address

Vice-chancellor for Research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd.

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences

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

Qazvin University of Medical Sciences

Full name of responsible person

Behzad Bijani

Position

Associate Professor of Infectious diseases

Other areas of specialty/work

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Person responsible for scientific inquiries

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Behzad Bijani

Position

Infectious diseases specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical sciences

Full name of responsible person

Behzad Bijani

Position

Associate Professor of Infectious diseases

Other areas of specialty/work

Street address

Buali Sina Hospital

City

Qazvin

Postal code

Phone

Fax

Email

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