

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of immune response to hepatitis B vaccine in simultaneous injections of Tetanus-diphtheria and B hepatitis vaccines with hepatitis B vaccine alone in Azahra staff having anti-HBs Ab lower than 100 IU/ml

Protocol summary

Summary

The aim of this study is to determine the cumulative effect of Tetanus-diphtheria vaccine (Td) in immune response emission against hepatitis B vaccine. This is a Randomized Clinical Trial (RCT), not blinded, unicenter, phase III study while placebo was not applied. The population of the study comprised nurses and staff of surgery ward at Alzahra hospital in Isfahan city having less than 100 IU/ml of hepatitis B antibody. Inclusion criteria included individuals whose immune system was not deficient whilst they were HBs Ag negative. Furthermore, those who were previously vaccinated were included in the study, unless they had 100 IU/ml or higher level of Hepatitis B Antibody. Exclusion criteria comprised individuals having hypersensitivity to B hepatitis vaccine. Since all of the staff of Alzahra hospital have health documents and are vaccinated against hepatitis B, individuals having less than 100 IU/ml will be recognizable. All of the individuals were randomly assigned either in intervention or control group in accordance with random number table. Control group was intramuscularly (IM) vaccinated through 40 microgram of recombinant HBsAg (rHBsAg) produced by CUBA-SIA company in the months of 0,1 and 6. The intervention group was vaccinated as well as control group schedule except that it simultaneously was vaccinated by adult Tetanus and Diphtheria (Td) vaccine. Finally, Antibody titer will be compared, after one and six months of the last vaccination, in the above mentioned groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051015999N2**
Registration date: **2014-08-06, 1393/05/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-06, 1393/05/15

Registrant information

Name

Roya Taleban

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Isfahan University of Medical Sciences

Expected recruitment start date

2013-02-14, 1391/11/26

Expected recruitment end date

2013-08-17, 1392/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of immune response to hepatitis B vaccine in simultaneous injections of Tetanus-diphtheria and B

hepatitis vaccines with hepatitis B vaccine alone in Azahra staff having anti-HBs Ab lower than 100 IU/ml

Public title

Effect of Tetanus-diphtheria vaccine in promotion of immune response against hepatitis B vaccine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Individuals being Hepatitis B Antigen (HBsAg) negative whilst they were vaccinated against B hepatitis and their antibody titers would be lower than 100 IU/ml. Lack of primary or acquired immune deficiency Exclusion criteria: Individuals will be excluded from the study and they will be treated if their status of hypersensitivity is recognized.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **280**

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City

Isfahan

Postal code

Approval date

2013-01-14, 1391/10/25

Ethics committee reference number

191049

Health conditions studied

1

Description of health condition studied

Hepatitis B

ICD-10 code

B18

ICD-10 code description

Chronic viral hepatitis

Primary outcomes

1

Description

Hepatitis B Antibody titer

Timepoint

1 and 6 months after vaccination

Method of measurement

By ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: This intervention was implemented by 40 microgram of rHBsAg produced by CUBA-SIA Company, while Tetanus-diphtheria vaccine (Td [0.5ml of toxoid produced at Pasteur Institute]) was simultaneously injected in the first application of rHBsAg in two different sites and the former vaccination continued one and six months later. All of the vaccination programs were implemented through intramuscular injections.

Category

Prevention

2

Description

Intervention 2: 40 microgram of recombinant HBsAg (rHBsAg) produced by CUBA-SIA company in months of 0, 1 and 6

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

Street address

Al-Zahra University Hospital, Sofeh Blvd., Isfahan, Iran.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Isfahan University of
Medical Sciences

Full name of responsible person

Peyman Adibi

Street address

Vice Chancellor for Research, Isfahan University of
Medical Sciences, Hezar-jarib St., Azadi Sq., Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Roya Taleban

Position

Resident of Community Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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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