

# 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)

###### Phone

+98 31 3792 2542

###### Email address

r.taleban@med.mui.ac.ir

##### 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

### Contact

**Name of organization / entity**

Bu-Ali Sina University

**Full name of responsible person**

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**Position**

PhD Candidate of Immunology

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## Person responsible for updating data

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**Position**

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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*