

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effects of short-term Atorvastatin treatment on vaccination efficacy in nonresponder persons to Hepatitis B vaccine

#### Protocol summary

##### Summary

Fifty two person of vaccinated individuals who have HBsAb <10 after 3 dose hepatitis B vaccination and with negative HBc Ab, HBs Ab, HBs Ag are included. Exclusion criteria are: positive serologic evidence of Hepatitis B infection- chronic use of Atorvastatin- immunosuppressive illness. Included individuals will be allocated randomly in 2 groups: group A: will receive one 40 mg Atorvastatin tablet orally per day for 10 days and in 5th day 1 dose of recombinant yeast-derived Hepatitis B vaccine intramuscular in left deltoid muscle; group B: will receive one placebo tablet orally per day for 10 days and in 5th day 1 dose of recombinant yeast-derived Hepatitis B vaccine intramuscular in left deltoid muscle. HBsAb will be measured in serum 4-8 weeks after vaccination in both groups with quantitative ELIZA method. Interlukins measurement with PCR method after white blood cell culture of both groups and exposed with vaccine in vitro, will be done. Then all data will be analyzed with SPSS software.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109147556N1**  
Registration date: **2011-12-20, 1390/09/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-12-20, 1390/09/29

##### Registrant information

###### Name

Nematollah Jonaidi Jafari

###### Name of organization / entity

Baqiyatallah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8860 0062

###### Email address

jonaidi@bmsu.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Baqiyatallah University of Medical Sciences

###### Expected recruitment start date

2011-09-23, 1390/07/01

###### Expected recruitment end date

2012-07-20, 1391/04/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effects of short-term Atorvastatin treatment on vaccination efficacy in nonresponder persons to Hepatitis B vaccine

###### Public title

Effects of Atorvastatin on Hepatitis B vaccination efficacy

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: HbsAb<10 after 3 dose hepatitis B vaccination- negative HBsAb- negative HBcAb- negative HBsAb. Exclusion criteria: positive serologic evidence of Hepatitis B infection- chronic use of Atorvastatin- immunosuppressive illness

###### Age

No age limit

###### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 52

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiyatallah University of Medical Sciences Ethics Committee

##### Street address

Baqiyatallah University of Medical Sciences, Mollasadra street, Vanak Sq.

##### City

Tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

28

## Health conditions studied

### 1

#### Description of health condition studied

Immunization against Viral Hepatitis B

#### ICD-10 code

Z24.6

#### ICD-10 code description

Need for immunization against Viral Hepatitis

## Primary outcomes

### 1

#### Description

HBsAb level in serum

#### Timepoint

Before Atorvastatine use and 1 month after vaccination

### Method of measurement

Quantitative ELIZA

### 2

#### Description

IL-4 , IL17 , TGFB , IFN-gamma

#### Timepoint

After WBC culture and exposure with vaccine in vitro

#### Method of measurement

Polymerase Chain Reaction (PCR)

## Secondary outcomes

### 1

#### Description

Immunization against viral hepatitis B

#### Timepoint

Before and 1 month after vaccination

#### Method of measurement

Quantitative ELIZA

## Intervention groups

### 1

#### Description

Control Group: will receive one placebo tablet orally per day for 10 days and in 5th day 1 dose of recombinant yeast-derived Hepatitis B vaccine intramuscular in left Deltoid muscle.

#### Category

Placebo

### 2

#### Description

Intervention Group: will receive one 40 mg Atorvastatin tablet orally per day for 10 days and in 5th day 1 dose of recombinant yeast-derived Hepatitis B vaccine intramuscular in left Deltoid muscle

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baqiyatallah University of Medical Sciences center of Military Health Researches

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr Hasan Saadat

**Street address**

Baqiyatallah University of Medical Sciences,  
Mollasadra strett, Vanak Sq.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Baqiyatallah 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**

Baqiyatallah Medical Sciences University

**Full name of responsible person**

Dr Nematollah Jonaidi Jafari

**Position**

Head of Center for Military Health Researches

**Other areas of specialty/work****Street address**

Baqiyatallah University of Medical Sciences,  
Mollasadra strett, Vanak Sq.

**City**

Tehran

**Postal code****Phone**

+98 21 8860 0062

**Fax****Email**

jonaidi@bmsu.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr Nematollah Jonaidi Jafari

**Position**

Specialist in Infectious disease

**Other areas of specialty/work****Street address**

Baqiyatallah University of Medical Sciences,  
Mollasadra strett, Vanak Sq.

**City**

Tehran

**Postal code****Phone**

+98 218860062

**Fax****Email**

jonaidi@bmsu.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr Nematollah Jonaidi Jafari

**Position**

Specialist in infectious disease

**Other areas of specialty/work****Street address**

Baqiyatallah University of Medical Sciences,  
Mollasadra strett, Vanak Sq.

**City**

Tehran

**Postal code****Phone**

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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*