Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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)

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+98 21 8860 0062

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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 Siences 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
Befor and 1 month after vaccination
Method of measurement
Quantitative ELIZA

Intervention groups

1

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

2

Description
Intervention Group:will recive one 40 mg Atorvastatin tablet orally per day for 10 days and in 5th day 1 dose of recombinant yeaset-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 Reaserches
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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