

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Influence double dose compared with single dose of hepatitis B vaccine on immunity in the nurses with Ab titration less than 10 Mlu/ml

Protocol summary

Summary

The purpose of this study was to compare influence double dose and single dose of hepatitis B vaccine on immunity in the nurses, It's a clinical trial. Inclusion criteria included: The nurse of one of the public hospitals in Rasht; Ab titration less than 10Mlu/ml. Exclusion criteria included: Consent to participate in this project. The study subjects are 1250 nurses after filling the questioners including demographic data (gender, age, work history, body mass index) health behaviors (smoking, alcohol) comorbidities (diabetes, cancer, chronic liver diseases, dialysis, ...) and history of vaccination, 5 ml blood samples were taken from them and antibody is identified and then the nurses with Ab titration less than 10 Mlu/ml will be divided to two groups by random block, single dose of hepatitis B vaccine will be injected in the first group and double dose for the second group then after one month Ab titration will be checked again, It won't receive further doses of vaccine if Ab titration is more than 10 Mlu/m, if Ab titration is less than 10Mlu/ml, two doses of vaccine will be injected one month and six months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405051155N18**

Registration date: **2014-09-08, 1393/06/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-08, 1393/06/17

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences,
Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 1553 5116

Email address

info@gldrc.org

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence double dose compared with single dose of hepatitis B vaccine on immunity in the nurses with Ab titration less than 10 Mlu/ml

Public title

Comparison of influence double dose and single dose of hepatitis B vaccine on immunity in the nurses

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The nurse of one of the public hospital in Rasht; Ab titration less than 10Mlu/ml Exclusion criteria: Consent to participate in this project

Age

No age limit
Gender
Both
Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **1250**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences, ethics committee gastrointestinal and liver diseases research

Street address

Gastrointestinal and liver disease research center, Razi hospital, Sardar Jangal avenue.

City

Rasht

Postal code

41448-95655

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

ش-171

Health conditions studied

1

Description of health condition studied

Hepatitis

ICD-10 code

K75.9

ICD-10 code description

Inflammatory liver disease, unspecified

Primary outcomes

1

Description

Increasing of antibody titration against hepatitis B more than 10Mlu/ml

Timepoint

On arrival, one month and six months after injection of hepatitis B vaccine

Method of measurement

blood

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group are nurses who have Ab titration of anti hepatitis B less than 10 Mlu/ml will be inoculated double dose vaccine in one arm and Ab titration will be checked one month later, if they have Ab titration less than 10 Mlu/ml, It'll be vaccinated again like the first method and It'll be checked five months later, they have Ab titration less than 10 Mlu/ml will be revaccinated.

Category

Prevention

2

Description

Control group are nurses who have Ab titration of anti hepatitis B less than 10 Mlu/ml will be inoculated single dose vaccine in one arm and Ab titration will be checked one month later, if they have Ab titration less than 10 Mlu/ml, It'll be vaccinated again like the first method and It'll be checked five months later, they have Ab titration less than 10 Mlu/ml will be revaccinated

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal clinic of Razi hospital

Full name of responsible person

Farahnaz Joukar

Street address

Gastrointestinal and Liver Diseases Research Center, Razi hospital, Sardare Jangal avenue

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vince chancellor for reaserch Guilan University of Medical Sciences

Full name of responsible person

Dr Rasool Tabari Khomeirani

Street address

Vince chancellor for reaserch Guilan University of Medical Sciences, Shahid Sadati street, Namjoo street, Rasht, Guilan

City

Rasht

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

Yes

Title of funding source

Vince chancellor for reaserch Guilan 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**

Gastrointestinal and liver disease research center

Full name of responsible person

Farahnaz Joukar

Position

Assistant of gastrointestinal and liver disease research center (GLDRC)

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

Gastrointestinal and liver disease research center, Razi hospital, Sardar Jangal Ave.

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Fax**Email**

F_Jokar@gums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Gastrointestinal and liver disease research center

Full name of responsible person

Dr.Fariborz Mansour-Ghanaei

Position

Head / Full professor of internal medicine and gastroenterology

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

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Person responsible for updating data

Contact**Name of organization / entity**

Gastrointestinal and liver disease research center

Full name of responsible person

Dr. Maryam Bakhshandeh

Position

General physician

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

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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