

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

To evaluate the immunization of HBV vaccine with double dose comparing standard dose in chronic liver disease patients in Isfahan city 2010-2011

Protocol summary

Summary

This study is aimed to assess the effects of hepatitis B vaccine with double dose comparing with the standard dose in chronic hepatic disease patients. A total of 64 patients with hepatitis c or hepatitis induced cirrhosis aged 18-65 and no history of hepatitis B or vaccination against hepatitis B and 32 healthy volunteers, as control group, are recruited. HBSAg and HBV Ab titers are checked for all participants in both groups. If HBSAg is negative and Ab titer is less than 10mIU/ml, the participants are enrolled in the study. HBV vaccine with standard dosage 1ml (20micg/ml) is injected to all healthy participants in control group and 32 patients who are selected randomly from HCV positive group and (HBV vaccine) with double dosage (2ml) is injected to 32 remaining HCV positive patients, intra muscular, three times (months 0, 1, and 6). The Ab titer is checked for all participants one month after the 3rd vaccination the results will be compared between groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902153873N1**

Registration date: **2010-10-29, 1389/08/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-29, 1389/08/07

Registrant information

Name

Afshin Tahmasbi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1628 3356

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tahmasbi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the immunization of HBV vaccine with double dose comparing standard dose in chronic liver disease patients in Isfahan city 2010-2011

Public title

To evaluate the immunization of HBV vaccine with double dose comparing standard dose in chronic liver disease patients in Isfahan city 2010-2011

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-65 years old, documented chronic HCV positive or cirrhosis Exclusion criteria: previously HBV vaccination or HBV positive, alcoholic cirrhosis or hepatitis, immune deficiency, CKD with GFR<60ml/min/1.73m² 5, autoimmune hepatitis or cirrhosis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences

Street address

Hezar jarib St., Isfahan

City

Isfahan

Postal code

Approval date

2008-08-11, 1387/05/21

Ethics committee reference number

187037

Health conditions studied

1

Description of health condition studied

Chronic viral hepatitis C

ICD-10 code

B18.2

ICD-10 code description

Chronic viral hepatitis C

Primary outcomes

1

Description

Anti HBS titer

Timepoint

Before & 1 month after intervention

Method of measurement

ELISA reader

Secondary outcomes

empty

Intervention groups

1

Description

HBV vaccine (Hepavax-Gene), in months 0, 1, and 6, intramuscular injection

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Research center sedighe tahere-infectious department

Full name of responsible person

Dr. Afshin Tahmasbi

Street address

Sedighe Tahere Research center, Khoram St., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research

Street address

Isfahan University of Medical Sciences, Hezar jerib Street, Isfahan

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Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

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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