

# 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

##### Email address

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/1.73m<sup>2</sup> 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

**City**

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

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Mohammad Minakari  
**Position**  
Assistant Prof. of Gastroenterology  
**Other areas of specialty/work**  
**Street address**  
Internal Medicine Unit, School of Medicine, Isfahan  
University of Medical Sciences  
**City**  
Isfahan  
**Postal code**  
**Phone**  
+98 31 1625 5555  
**Fax**  
**Email**  
mminakari@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Mohammad Minakari  
**Position**  
Assistant Prof. of Gastroenterology  
**Other areas of specialty/work**  
**Street address**  
Internal Medicine Unit, School of Medicine, Isfahan  
University of Medical Sciences  
**City**  
Isfahan  
**Postal code**

**Phone**  
+98 31 1625 5555  
**Fax**  
**Email**  
mminakari@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Afshin Tahmasbi  
**Position**  
Internal Medicine Resident  
**Other areas of specialty/work**  
**Street address**  
Alzahra Hospital, Isfahan  
**City**  
Isfahan  
**Postal code**  
**Phone**  
+98 31 1628 3356  
**Fax**  
**Email**  
tahmasbi.afshin@yahoo.com  
**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*