

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A comparative evaluation of combination therapy of Lamivudine and Colchicine comparing with Lamivudine and placebo in clinical and laboratory improvement of chronic hepatitis B

#### Protocol summary

##### Summary

The purpose of this study is to assess the efficacy of combination therapy of Lamivudine and Colchicine comparing with Lamivudine alone for treatment of chronic viral hepatitis B. In this double blind study, 100 patients with serologic and biochemical confirmed chronic hepatitis B will be randomized into treatment group (Lamivudine 100mg daily and Colchicine 0.5 mg daily, for 6 months) or control group (Lamivudine 100mg daily and placebo once daily, for 6 months). Patients should be HBS Ag positive serologically and their alanine aminotransferase levels (ALT) be at least two fold of normal range will be enrolled in the study. Alcoholic patients, HCV antibody positive patients, patients with HIV infection, metabolic liver disease, right cardiac heart failure, or hypersensitivity to drugs will be excluded. At the end of therapy, serum ALT, serum bilirubin, serum Albumin and PT will be evaluated and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138807112539N1**

Registration date: **2009-11-08, 1388/08/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2009-11-08, 1388/08/17

##### Registrant information

###### Name

Amir Hassanpour

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1367 4405

###### Email address

drhassanpor@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2009-07-06, 1388/04/15

##### Expected recruitment end date

2010-06-22, 1389/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative evaluation of combination therapy of Lamivudine and Colchicine comparing with Lamivudine and placebo in clinical and laboratory improvement of chronic hepatitis B

##### Public title

Assessment of Colchicine efficacy in treatment of chronic hepatitis B

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: positive HBS Ag, confirmed chronic hepatitis B, ALT level at least twofold of normal range  
Exclusion criteria: positive HCV Ab, positive HIV Ab, Alcohol abuse, Presence of auto immune hepatitis,

metabolic liver disease, right cardiac failure or pulmonary hypertension, low compliance, allergic reaction to drugs or severe side effect of drugs, presence of decompensate cirrhosis (PT>20 sec and ALb<3 gr/dl)

#### Age

From **15 years** old to **70 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Randomized, double-blind, parallel, controlled trial

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Shahid Shiroodi Avenue, Allamolhoda Str

##### City

Arak

##### Postal code

3819693345

##### Approval date

empty

##### Ethics committee reference number

10-19-5-88

## Health conditions studied

### 1

#### Description of health condition studied

Chronic viral hepatitis B

#### ICD-10 code

B 18.1

#### ICD-10 code description

Chronic viral hepatitis B

## Primary outcomes

### 1

#### Description

Treatment of chronic hepatitis B

#### Timepoint

One month before intervention and one month after intervention

#### Method of measurement

Laboratory measurement of serum ALT- Albumin-bilirubin and PT

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Lamivudine, 100 mg daily and Colchicine 0.5mg daily for 6 months

#### Category

Treatment - Drugs

### 2

#### Description

Lamivudine 100 mg daily and placebo once daily for 6 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gastroenterology Clinic, Amiralmomenin Hospital

##### Full name of responsible person

Dr Amir Hassanpour

##### Street address

Amiralmomenin Hospital

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Ali Fani

##### Street address

Amiralmomenin Hospital

##### City

Arak

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

Yes

**Title of funding source**  
Arak 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**  
Arak University of Medical Sciences

**Full name of responsible person**  
Dr Amir Hassanpour

**Position**  
Internal Medicine Resident

**Other areas of specialty/work**

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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*