Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 hepatits B will be randomize into treatment group (Lamivudine l00mg daily and Colchicine 0.5 mg daily, for 6 months) or control group (Lamivudine l00mg 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
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Arak University of Medical Sciences
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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 sever 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
Gastroentrology Clinic, Amiralmomenin Hospital

Full name of responsible person
Dr Amir Hassanpour

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Ali Fani

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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

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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