Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of Curcumin in the improving patients with autoimmune hepatitis

Protocol summary

Study aim

Evaluation of the effectiveness of Curcumin in the improving patients with autoimmune hepatitis (HIA) referred to Imam Ali research hospital and Edaalat clinic of Zahedan

Design

A randomized clinical trial with placebo and treatment with Curcumin groups, 2 Blinded, including 68 patients, randomized, The rand function of Excel software was used for randomization.

Settings and conduct

This study will be performed on 68 patients with HIA referred to Imam Ali Research Hospital and Edaalat Clinic of Zahedan city. Patients in the Curcumin treatment group will receive the standard HIA treatment protocol with 500 mg per day of curcumin for 2 months and in the placebo group will receive the standard HIA treatment protocol with placebo for 2 months (with the same duration). Finally, laboratory tests (CBC, Bill, Cholesterol, ANA, ALT, ALP, AST and IgG) will be measured in 2 time periods before curcumin consumption and 2 months after curcumin consumption to determine the effect of Curcumin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range from 18 to 50 years, Patients with HIA based on diagnostic criteria (abnormalities of AST and ALT levels, hypergammaglobulinemia and increased serum IgG levels), positive serological findings (SMA, ANA and anti-LKM1). Exclusion criteria: Primary Biliary Cirrhosis, Primary Sclerosing Cholangitis, Wilson's or Hemochromatosis, Liver Cirrhosis, Fulminant Liver Failure, history of drug treatment with hepatotoxicity

Intervention groups

Placebo group: patients with standard HIA treatment protocol with placebo for 2 months, Experimental group: patients with standard HIA treatment protocol with 500 mg/day curcumin for 2 months

Main outcome variables

Laboratory tests complete blood count (CBC), Bilirubin (Bill), antinuclear antibody (ANA), alanine transaminase (ALT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), Immunoglobulin G (IgG)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221112056476N1**
Registration date: **2024-03-06, 1402/12/16**
Registration timing: **prospective**

Last update: **2024-03-06, 1402/12/16**
Update count: **0**

Registration date

2024-03-06, 1402/12/16

Registrant information

Name

Samira Shahraki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-10, 1402/12/20

Expected recruitment end date

2025-02-08, 1403/11/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Curcumin in the improving patients with autoimmune hepatitis

Public title
Evaluation of the effectiveness of Curcumin in the improving patients with autoimmune hepatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range from 18 to 50 years Suffering from autoimmune hepatitis based on diagnostic criteria (abnormalities of AST and ALT levels, hypergammaglobulinemia and increased serum IgG levels), positive serological findings (SMA, ANA and anti-LKM1) and histological findings and confirmed by an adult gastroenterologist
Exclusion criteria:
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
People have been blinded: Participant and Data analyzer Curcumin and placebo are completely similar in shape, color and administration method
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
University 25, University Street, Zahedan, Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
۹۸۱۶۷۴۳۱۱۱
Approval date
2023-06-18, 1402/03/28
Ethics committee reference number
IR.ZAUMS.REC.1402.133

Health conditions studied

1

Description of health condition studied
Autoimmune hepatitis
ICD-10 code
K75.4
ICD-10 code description
Autoimmune hepatitis

Primary outcomes

1

Description
Complete Blood Count (CBC)
Timepoint
Before curcumin consumption and 2 months after curcumin consumption
Method of measurement
Blood cells count

2

Description
Bilirubin (Bill)
Timepoint
Before curcumin consumption and 2 months after curcumin consumption
Method of measurement
Based on laboratory tests

3

Description
Antinuclear antibody
Timepoint
Before curcumin consumption and 2 months after curcumin consumption
Method of measurement
ELISA

4

Description
Alanine Transaminase (ALT)
Timepoint

Before curcumin consumption and 2 months after curcumin consumption

Method of measurement

Based on laboratory tests

5

Description

Alkaline Phosphatase (ALP)

Timepoint

Before curcumin consumption and 2 months after curcumin consumption

Method of measurement

Based on laboratory tests

6

Description

Aspartate Aminotransferase (AST)

Timepoint

Before curcumin consumption and 2 months after curcumin consumption

Method of measurement

Based on laboratory tests

7

Description

Immunoglobulin G (IgG)

Timepoint

Before curcumin consumption and 2 months after curcumin consumption

Method of measurement

ELISA

Secondary outcomes

1

Description

Response to treatment

Timepoint

2 months after consumption the Curcumin

Method of measurement

Based on the normalization of Aminotransferases and Gammaglobin levels less than UMN

Intervention groups

1

Description

Intervention group: Patients with standard autoimmune hepatitis treatment protocol with 500 mg per day of curcumin for 2 months

Category

Treatment - Drugs

2

Description

Control group: Patients with standard autoimmune hepatitis treatment protocol with placebo for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Research Hospital

Full name of responsible person

samira shahraki

Street address

Imam Ali Research Hospital, Persian Gulf Highway, Zahedan, Iran

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2

Recruitment center

Name of recruitment center

Edaalat Clinic of Zahedan

Full name of responsible person

Hamed taheri

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Health 13, Health Boulevard, Zahedan, Iran

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Title of funding source
Zahedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Samira Shahraki
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Physiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available