

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of anti-TN-alpha (Infliximab) on necrosis, inflammation, fibrosis and overall survival in patients with cryptogenic cirrhosis.

Protocol summary

Summary

Aim: evaluation of the effects of anti-TNF-alpha (Infliximab) on necrosis, inflammation, fibrosis and overall survival in patients with cryptogenic cirrhosis. Inclusion criteria: existence of proved cryptogenic cirrhosis; lack of experience with infliximab treatment in cirrhosis due to it. Exclusion criteria: decompensated cirrhosis; active or latent tuberculosis. Case group: patients with non decompensated cryptogenic cirrhosis. Sample size: 30 patients including 15 patients in intervention group and 15 patients in control group. intervention: treatment with anti-TNF-alpha (Infliximab) drug. Time: first phase: three month, and second phase: three month. Primary outcome measure: improvement of patient's MELD score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052228003N1**
Registration date: **2016-06-15, 1395/03/26**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-15, 1395/03/26

Registrant information

Name

Sanaz Taherpour

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 916 859 9857

Email address

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Recruitment status

Recruitment complete

Funding source

Research center for infectious diseases of digestive system, research affairs of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of anti-TN-alpha (Infliximab) on necrosis, inflammation, fibrosis and overall survival in patients with cryptogenic cirrhosis.

Public title

Effect of Infliximab on treatment of cirrhosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: existence of proved cryptogenic cirrhosis; lack of experience with infliximab treatment in cirrhosis due to it; having informed consent Exclusion criteria: Decompensated cirrhosis; active or latent tuberculosis; patient's trend to leaving the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic committee of Ahvaz Jundishpur
University of Medical Sciences

Street address

Ahvaz Jundishpur University of Medical Sciences-
Deputy of Research and Technology Development-
Research Ethical committee

City

Ahvaz

Postal code

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.AJUMS.REC.1395.63

Health conditions studied

1

Description of health condition studied

Cryptogenic cirrhosis

ICD-10 code

K74.6

ICD-10 code description

Other and unspecified cirrhosis of liver

Primary outcomes

1

Description

improvement of MELD score

Timepoint

0- 3th month- 6th month

Method of measurement

according to creatinine, billirubine, and INR- Range: 6-40

Secondary outcomes

1

Description

decrease of numbers of hospitalization and decrease of
cirrhosis complications

Timepoint

0- 3th month- 6th month

Method of measurement

Evaluation of patient's medical file and disease
progression

Intervention groups

1

Description

control group: traditional conservative treatments

Category

Treatment - Other

2

Description

Intervention group: traditional conservative treatments +
infiximab (loading dose: 3 mg/kg & maintenance dose: 3
mg/kg for 12 weeks; q 2 weeks)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic of Imam Khomeini hospital of Ahvaz

Full name of responsible person

Sanaz Taherpour

Street address

City

Ahvaz

2

Recruitment center

Name of recruitment center

Gastroenterology Ward of Imam Khomeini hospital of
Ahvaz

Full name of responsible person

Sanaz Taherpour

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center for infectious diseases of digestive system, research adjutancy of Ahvaz Jundishapur

Full name of responsible person

Doctor Behzad Sharif Makhmalzadeh

Street address

Ahvaz Jundishapur University of Medical Sciences - research adjutancy

City

Ahvaz

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

Yes

Title of funding source

Research center for infectious diseases of digestive system, research adjutancy of Ahvaz Jundishapur

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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sanaz Taherpour

Position

Medical student

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Person responsible for updating data

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Seied Ali Mard

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Physiologist, Phd

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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