

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Assessment of pentoxifyllin effects on the serum level of inflammatory cytokines(IL-6, IL-8, TNF- α) and liver transaminases in patient with non alcoholic steatohepatitis

Protocol summary

Summary

The triple-blind study in 30 patients with non alcoholic steatohepatitis in gastroenterology clinics office and hospitals in Kerman AfzaliPour referred projects will be selected. They are listed according to the criteria of the study and were randomly divided into experimental and control groups. Clinical trial of pentoxifylline in NASH through the effect of inflammatory cytokines such as IL_6, IL-8 and TNF- α in Kerman will be studied. The intervention group had a tablet of pentoxifylline (400 mg) and the control group received a placebo three times a day for six months will be prescribed. At the time before, three months and six months later, the IL8, IL6, TNF- α and liver enzymes AST and ALT and BMI were measured. Finally all the collected data was analyzed using SPSS-18 and descriptive statistical tests will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015033021565N1**

Registration date: **2015-05-19, 1394/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-19, 1394/02/29

Registrant information

Name

Nadieh Baniasadi

Name of organization / entity

Kerman University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

baniasadi.n@gmail.com

Recruitment status

Recruitment complete

Funding source

kerman University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of pentoxifyllin effects on the serum level of inflammatory cytokines(IL-6, IL-8, TNF- α) and liver transaminases in patient with non alcoholic steatohepatitis

Public title

Pentoxifylline effects on the treatment of non alcoholic steatohepatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of non alcoholic steatohepatitis is with clinical and paraclinical criteria (elevated ALT and AST to 1.5 times more than normal and sonography confirmation of fatty liver). Exclusion criteria: Diabetes mellitus; hyperlipidemia; liver diseases(Serum level, ASMA, ANA, FERRITIN, a-1anti

trypsin, people with positive markers hepatitis B virus, hepatitis c & hepatitis a); drug users (Calcium channel blocker, B blocker, amiodarone, glucocorticoids, strogen,...); alcoholic users; people who intervened before and during acute or chronic liver or systemic disease.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

Ibn Sina street - Samia Crossroads -kerman

City

kerman

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

k/91/331

Health conditions studied

1

Description of health condition studied

non alcoholic steatohepatitis

ICD-10 code

k76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

ALT

Timepoint

Before the intervention, third month after intervention, sixth month after intervention

Method of measurement

Blood Exam

2

Description

AST

Timepoint

Before the intervention, third month after intervention, sixth month after intervention

Method of measurement

Blood Exam

3

Description

BMI

Timepoint

Before the intervention, third month after intervention, sixth month after intervention

Method of measurement

height measurement with tape and weight measurement with digital scale

4

Description

IL-6

Timepoint

Before the intervention, sixth month after intervention

Method of measurement

Elisa Exam

5

Description

IL-8

Timepoint

Before the intervention, sixth month after intervention

Method of measurement

Elisa Exam

6

Description

TNF-a

Timepoint

Before the intervention, sixth month after intervention

Method of measurement

Elisa Exam

Secondary outcomes

empty

Intervention groups

1

Description

People in intervention group will treat with pentoxifylline for six months at a rate of one tablet of 400 mg three times a day. exercise and diet will advise for every one.

Category

Treatment - Drugs

2

Description

People in control group will treat with pelacebo for six months at a rate of one tablet three times a day. exercise and diet will advise for every one.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat clinic

Full name of responsible person

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Science

Full name of responsible person

Dr Nadieh Baniasadi

Street address

Somaieh junction (Tahmasb abad), Shariaty street ,
Deputy of Research and Technology of Kerman
University of Medical Sciences

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Science

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

Kerman Univercity of Medical Sciences

Full name of responsible person

Dr Nadieh Baniasadi

Position

Assisstant professor of gastroentrolology

Other areas of specialty/work

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hospital

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Name of organization / entity

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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