Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessment of pentoxifillin 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
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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 pentoxifillin 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; hyperlypidemia; liver diseases(Serum level, ASMA, ANA, FERRITIN, a-1anti

tripsin, people with positive markers hepaptitis B virus, hepatitis c & hepatitis a); drug users (Calsium channel blocker, B blocker, amiodarone, glucocorticoids, strogen,...); alcoholic users; people who intervened before and during acute or chronic liveror 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 mounth after intervention

Method of measurement
Blood Exam

2

Description
AST

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

Method of measurement
Blood Exam

3

Description
BMI

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

Method of measurement
height measurement with tape and weight measurement with digital scale

4

Description
IL-6

Timepoint
Before the intervention, sixth mounth after intervention

Method of measurement
Elisa Exam

5

Description
IL-8

Timepoint
Before the intervention, sixth mounth after intervention

Method of measurement
Elisa Exam

6

Description
TNF-a

Timepoint
bBfore the intervention, sixth mounth 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
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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