# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
**Name of organization / entity**
Kerman University of Medical Science
**Country**
Iran (Islamic Republic of)
**Phone**
+98 34 3243 7654
**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 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**
Assisstant professor of gastroentrology
**Other areas of specialty/work**
**Street address**
Eman Highway, next to Zendan junction, Afzalipoor hospital
**City**
Kerman
**Postal code**
**Phone**
+34 33222250
**Fax**
**Email**
baniasadi.n@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Kerman Univercity of Medical Sciences
**Full name of responsible person**
Dr Nadieh Baniasadi
**Position**
Assisstant professor of gastroentrology
**Other areas of specialty/work**
**Street address**
Eman Highway, next to Zendan junction, Afzalipoor hospital
**City**
Kerman
**Postal code**
**Phone**
+33 222250
**Fax**
**Email**
baniasadi.n@gmail.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kerman Univercity of Medical Sciences
**Full name of responsible person**
Dr Nadieh Baniasadi
**Position**
Assisstant professor of gastroentrology
**Other areas of specialty/work**
**Street address**

Eman Highway, next to Zendan junction, Afzalipoor hospital

**City**

Kerman

**Postal code**

**Phone**

+34 33222250

**Fax**

**Email**

baniasadi.n@gmail.com

**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*