

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Gemfibrozil for treatment of cigarette dependence

#### Protocol summary

##### Summary

(1) Objectives: This study aims at investigating the effectiveness Gemfibrozil on treatment of smoker's nicotine dependence in Kashan. (2) Design: This is a pretest-posttest experimental study. The intervention also includes a twelve-weeks follow-up course. (3) Methods: A sample of 76 eligible smokers will be recruited. That will be randomly allocated to either the experimental or the control groups. Smokers in the experimental group will receive Gemfibrozil while the smokers in the control group will receive placebo. Study instruments include fagestrom dependence scale, Minnesota Nicotine Withdrawal Scale and the exhaled CO2 detector. These instruments will be completed before intervention, weekly measure during 7 weeks of intervention and 8,11,14,19 weeks after beginning of intervention. (4) Inclusion Criteria: Having an age of 19-65 years; nicotine dependence based on DSM 5; lack of history of psychotic disorders; having negative results in opioid and amphetamines test; lacking diagnosis of chronic disease such as diabetes, blood pressure, cancer and etc; Not be pregnant. Exclusion criteria: Unwillingness to continue participating in the study; being pregnancy during study; uses drugs with contraindication or Interference with Gemfibrozil such as Anticoagulants, statins, other fibrates and niacin. (6) Intervention: The intervention of this study is 300 mg twice on day of Gemfibrozil. (7) Primary outcomes: The primary outcomes are Nicotine Withdrawal, nicotine dependence and smoking cessation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017101732057N3**

Registration date: **2017-11-01, 1396/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-01, 1396/08/10

##### Registrant information

###### Name

Mohamad Reza Davoudi

###### Name of organization / entity

Kashan University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 2999

###### Email address

davoudi-mr@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research Kashan University of Medical Sciences and Health Services

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2015-12-15, 1394/09/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Gemfibrozil for treatment of cigarette dependence

##### Public title

effect of Gemfibrozil for treatment of cigarette

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Having an age of 19–65 years; nicotine dependence based on DSM 5; lack of history of psychotic disorders; having negative results in opioid and amphetamines test; lacking diagnosis of chronic disease such as diabetes, blood pressure, cancer and etc; Not be pregnant. Exclusion criteria: Unwillingness to continue participating in the study; being pregnant during study; uses drugs with contraindication or Interference with Gemfibrozil such as Anticoagulants, statins, other fibrates and niacin.

#### Age

From **19 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **76**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

The population consisted of all smokers admitted to center treatment of drug abuse and smoking in Kargrnzhad psychiatric hospital. from all participation's that meets inclusion criteria, 38 participants for each group selected by Random assignment will be done, that by the use of computer-generated random numbers.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of kashan University of Medical Sciences and Health Services

##### Street address

Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

##### City

Kashan

##### Postal code

#### Approval date

2015-07-06, 1394/04/15

#### Ethics committee reference number

IR.KAUMS.REC.1394.29

## Health conditions studied

### 1

#### Description of health condition studied

nicotine dependence

#### ICD-10 code

F17

#### ICD-10 code description

Mental and behavioural disorders due to use of tobacco

## Primary outcomes

### 1

#### Description

smoking cessation

#### Timepoint

Before intervention; 1,2,3,4,5,6,7,8,11,14,19 after beginning of intervention.

#### Method of measurement

Expiratory CO2 concentration

### 2

#### Description

nicotine dependence

#### Timepoint

Before intervention; 1,2,3,4,5,6,7,8,11,14,19 after beginning of intervention.

#### Method of measurement

fagestrom nicotine dependence scale

### 3

#### Description

Nicotine Withdrawal

#### Timepoint

Before intervention; 1,2,3,4,5,6,7,8,11,14,19 after beginning of intervention.

#### Method of measurement

Minnesota Nicotine Withdrawal Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control Group: This group receives placebo for seven weeks

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Gemfibrozil 300 mg for twice daily mg for seven weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kargarnejad Psychiatric Hospital

**Full name of responsible person**

MD.Fateme Sadat Ghoreyshi

**Street address**

Kargarnejad psychiatric Hospital, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd Kashan

**City**

kashan

**Position**

M.Sc Candidate in Clinical Psychology

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

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

**City**

Kashan

**Postal code****Phone**

+98 31 5554 9111

**Fax****Email**

msc.davoudi.psy@gmail.comdavoudi-mr@kaums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

**Full name of responsible person**

Dr Qolam Ali Hamidi

**Street address**

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

**City**

Kashan

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

Yes

**Title of funding source**

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

**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**

Kashan University of Medical Sciences and Health Services

**Full name of responsible person**

Maohamadreza Davoudi

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences and Health Services

**Full name of responsible person**

Maryam Shahriyari

**Position**

Psychiatrist

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

Kargarnejad psychiatric Hospital, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

**City**

Kashan

**Postal code****Phone**

+98 31 5554 9111

**Fax****Email**

mshahriari80@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences and Health Services

**Full name of responsible person**

Maohamadreza Davoudi

**Position**

M.Sc Candidate in Clinical Psychology

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

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

**City**

Kashan

**Postal code**

**Phone**  
+98 31 5554 9111  
**Fax**  
**Email**  
**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*