Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 twelves-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 debate, 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

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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 debate, 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.

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