Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy and safety of outpatient alcohol treatment among people with alcohol use disorder referring to INCAS psychiatric clinic

Protocol summary

Study aim

General aim: Study of Efficacy and safety of alcohol treatment in INCAS psychiatric clinic Specific aims: The determine of patient retention in outpatient alcohol treatment for 12 weeks, The determine of efficacy of outpatient alcohol treatment to decrease use of alcohol, The determine of efficacy of outpatient alcohol treatment to decrease alcohol problems, The determine of efficacy of outpatient alcohol treatment to decrease severity of alcohol dependence, The determine of efficacy of outpatient alcohol treatment to improve liver function test(LFT), The determine of safety of outpatient alcohol treatment

Design

This study is a quasi-experimental(non-randomized) trial with a single-group design. This study has two stage: 1-preparation intervention protocol, 2-the study of safety and efficacy of intervention. In the first stage of labor, pharmacological interventions protocol(according to guideline on treatment of harmful use and alcohol dependence of the Ministry of Health and Medical Education) will be provided. Also psychological intervention based on guidelines for the psychological treatments of stimulant drug dependence and evidence-based national guidelines will be provided. In second stage of study,30 patients with alcohol use disorder was selected according to the inclusion criteria. The participants will receive drug treatment and psychological intervention. Finally the safety and efficacy of outpatient alcohol treatment will be evaluated.

Settings and conduct

Participants of the study are new patients who are referred to INCAS psychiatric clinic and fulfilling inclusion criteria. After the patients will sign written consent form, will be baseline assessment for them and then will be determined treatment program. The patients who are required to drug treatment for alcohol detox(moderate dependence will be measured with a SADQ score of between 15 and 30)will receive an alcohol treatment by benzodiazepines for 2 to 4 weeks. All patients will receive drug treatment for relapse prevention. Also they participate in individual psychological intervention per week for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Age: 18 to 65 years old 2.Diagnosis of alcohol use disorder based on DSM-5 3.written consent will be completed for all patients exclusion criteria: 1.Any Acute comorbid disorder such as Psychotic and has a tendency to suicide 2.There is no proportion with outpatient treatment

Intervention groups

In this study pharmacological interventions to detox by benzodiazepines and prevent relapse will be implemented. Also psychological intervention based on motivational interview and Cognitive–behavioral relapse prevention will be implemented. These session consisted of 12 weekly 45-minute.

Main outcome variables

Retention of patients in alcohol outpatient treatment for 12 weeks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170702034844N3**
Registration date: **2018-02-16, 1396/11/27**
Registration timing: **prospective**

Last update: **2018-02-16, 1396/11/27**
Update count: **0**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Alireza Noroozi

Name of organization / entity

Iranian National Center for Addiction Studies (INCAS)
Country
Iran (Islamic Republic of)
Phone
+98 21 5542 1144
Email address
noroozi_a@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences (TUMS),Vice-chancellor for Research

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2018-10-23, 1397/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and safety of outpatient alcohol treatment among people with alcohol use disorder referring to INCAS psychiatric clinic

Public title
Efficacy of outpatient treatment of alcohol use disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 18 to 65 years old Diagnosis of alcohol use disorder based on DSM-5 Providing informed written consent
Exclusion criteria:
Severe co-morbid psychiatric disorder including psychosis or suicide Inappropriate for outpatient treatment due to lack of family support, history of delirium tremens (DT) or seizures during previous alcohol withdrawal attempts Inappropriate for outpatient treatment due to severe alcohol dependence defined by score over 30 in SADQ test
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **31**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences (TUMS), Vice-Chancellor for Research
Street address
6th Floor, Central Building of Tehran University of Medical Sciences (TUMS), Ghods St., Keshavarz Blv. Tehran, Iran, Islamic Republic Of
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-01-08, 1396/10/18
Ethics committee reference number
IR.TUMS.VCR.REC.1396.4174

Health conditions studied

1

Description of health condition studied
Alcohol use disorder
ICD-10 code
F10.2
ICD-10 code description
A cluster of behavioural, cognitive, and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences

Primary outcomes

1

Description
Treatment retention
Timepoint
Weekly for 12 weeks
Method of measurement
Participation in weekly individual psychotherapy session

Secondary outcomes

1

Description
Alcohol use disorders screening
Timepoint
Baseline and weeks 4 and 12
Method of measurement
Alcohol Use Disorder Identification Test (AUDIT)

2

Description
Severity of alcohol dependence
Timepoint
Baseline and weeks 4 and 12
Method of measurement
Severity of Alcohol Dependence Questionnaire (SADQ)

3

Description
Alcohol addiction severity
Timepoint
Baseline and week 12
Method of measurement
Alcohol section of Addiction Severity Index (ASI)

4

Description
Aspartate Aminotransferase (AST)
Timepoint
Baseline and weeks 4 and 12
Method of measurement
Blood test

5

Description
Alanine Aminotransferase (ALT)
Timepoint
Baseline and weeks 4 and 12
Method of measurement
Blood test

6

Description
Gamma-Glutamyl Transferase (GGT)
Timepoint
Baseline and weeks 4 and 12
Method of measurement
Blood test

Intervention groups

1

Description
All patient who meet study eligibility criteria will receive outpatient fixed-schedule alcohol withdrawal treatment with benzodiazepines (diazepam) for 1 to 3 weeks according to national alcohol treatment guidelines if needed (score of Severity of Alcohol Dependence Questionnaire between 15 and 30) and then entered to replace prevention pharmacotherapy with naltrexone 50 mg daily till end of week 12. Furthermore all patients will receive psychological interventions including structured weekly individual psychotherapy session on alcohol relapse prevention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric Clinic, Iranian National Center for Addiction Studies (INCAS)
Full name of responsible person
Dr. Alireza Noroozi
Street address
No 486, South Kargar St., Qazvin Sq., Next to Farabi Hospital
City
Tehran
Province
Tehran
Postal code
664 - 14145
Phone
+98 21 5542 1144
Fax
+98 21 5541 2232
Email
a_r_noroozi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ms. Karimi
Street address
6th Floor, Central Building of Tehran University of Medical Sciences (TUMS), Ghods St., Keshavarz Blv.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3616
Email
rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Alireza Noroozi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No 486, South Kargar St., Qazvin Sq., Next to Farabi Hospital
City
Tehran
Province
Tehran
Postal code
1336616357
Phone
+98 21 5541 5225
Fax
Email
a_r_noroozi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Alireza Noroozi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No 486, South Kargar St., Qazvin Sq., Next to Farabi Hospital
City
Tehran
Province
Tehran
Postal code
1336616357
Phone
+98 21 5541 5225
Fax
Email
a_r_noroozi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Alireza Noroozi
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No 486, South Kargar St., Qazvin Sq., Next to Farabi Hospital
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Tehran
Province
Tehran
Postal code
1336616357
Phone
+98 21 5541 5225
Fax
Email
a_r_noroozi@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Participants data file: The participants data without identifying information will be available after completion of the study. Clinical study report: The clinical study report will be available after completion of the study.

When the data will become available and for how long

July 2019

To whom data/document is available

Researchers of psychiatric disorders clinical studies

Under which criteria data/document could be used

Using study data for systematic reviews and meta-analysis studies ispermitted.

From where data/document is obtainable

Dr. Alireza Noroozi Psychiatric Clinic, Iranian National Center for Addiction Studies (INCAS) Address: No 486, South Kargar St, Tehran, Iran Email: a_r_noroozi@yahoo.com

What processes are involved for a request to access data/document

The data request need to clearly define data needs. The study contact person will provide available data within 1 week after receiving the req

Comments

NA