

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Cytisine versus nicotine for smoking cessation in hospitalized psychiatric patients.

Protocol summary

Study aim

Comparison the effect of Cytisine versus nicotine for smoking cessation in psychiatric patients

Design

Parallel Clinical trial with control group

Settings and conduct

Intervention groups include patients over the age of 18 in the psychiatric ward of the Taleghani Hospital who tend to quit cigarette. To one group chewing gum or nicotine patch is given for a 2-week treatment period and the other group receive the Tabax tablet for 25 days according to the approved protocol of the manufacturer. Patients are then evaluated for signs and responses in the first week and months 1, 2 and 6 respectively

Participants/Inclusion and exclusion criteria

Aged over 18; Daily cigarette smoking; The desire to quit smoking Do not be pregnant; No recent (past 2 weeks) cardiovascular events.

Intervention groups

Intervention is done in two groups: The first intervention group receive chewing gum or nicotine patch for a 2-week treatment period. The second intervention group is given Tabex tablet according to the protocol approved by the company.

Main outcome variables

Smoking cessation; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N16**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **prospective**

Last update: **2019-01-14, 1397/10/24**

Update count: **0**

Registration date

2019-01-14, 1397/10/24

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cytisine versus nicotine for smoking cessation in hospitalized psychiatric patients.

Public title

Cytisine versus nicotine for smoking cessation in hospitalized psychiatric patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years of age Daily smokers Motivated to quit

Exclusion criteria:

Pregnant or breast-feeding women Enrolled in another cessation program or study Systolic blood pressure above 150 mm Hg Diastolic blood pressure above 100 mm Hg Cardiovascular event in the 2 weeks before study enrollment

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Vali-e-asr ave., Niyayesh junction

City

Tehran

Province

Tehran

Postal code

1991953381

Approval date

2018-02-09, 1396/11/20

Ethics committee reference number

ir.sbm.u.phnm.1396.872

Health conditions studied

1

Description of health condition studied

Smoking cessation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Smoking cessation

Timepoint

1 week and at 1, 2 and 6 months after quit day

Method of measurement

1)mood and physical symptoms scale (MPSS)The AUDIT alcohol 2)consumption questions (AUDIT-C)Confirmatory factor analyses and 3)reliability of the modified cigarette evaluation questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

1 week and at 1, 2 and 6 months after quit day

Method of measurement

1)Mood and physical symptoms scale (MPSS) 2)The AUDIT alcoholconsumption questions (AUDIT-C)

Intervention groups

1

Description

Intervention group: Patients taking tabex tablets of Sopharma Bulgaria in the form of protocol approved by the company.The Cytisine protocol is as follows:Days 1 to 3: 6 tablets a day, 4 to 12 days daily 5 tablets, 13 to 16 days daily 4 tablets, days 17 to 20 daily 3 tablets and days 21 to 25 daily 2 tablets.Then the patients are evaluated in the first week and in the 1st, 2nd and 4th months after the start of the pill.

Category

Other

2

Description

Intervention group: Patients using nicotine gum or patch. Patients use nicotine gum or nicotine patches for 8 weeks. Then, the patients are examined at the first week and 1, 2, and 4 months after starting the use.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person
Zeynab Gholamzadeh Sani
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Sponsors / Funding sources

1

Sponsor

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Pharma student
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information are confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available