

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Survey effectiveness of Combined Herbal Remedies with Bupropion on cigarette smoking in patients referring to quit cigarette clinic - A Randomized Clinical Trial

Protocol summary

Study aim

The Effect of Combined Herbal Remedies with Bupropion Discrimination on the Reduction of Smoking in Patients Referring to the Smoking cessation Clinic - A Randomized Clinical Trial Determination of cigarette smoking in the bupropion-buprenorphine group. Determine cigarette switching in the bupropion alone group. Determine the change in consumption of bupropion for the smoker group in chamomile Determination of the difference between smoking in both groups of bupropion and bupropion alone and bupropion with chamomile

Design

Clinical trials with a community-based control group with parallel, double-blind, accessible groups

Settings and conduct

In smoking cessation centers, municipal health centers in 1, 2 and 3 areas of Tehran, as well as the smoking cessation clinic of the anti-smoking community and random blocks were unaware of available participants in these centers.

Participants/Inclusion and exclusion criteria

Individuals aged 20 to 65 years old with more than 10 cigarettes per day and with a history of smoking for at least one year. Drug use is not recommended for the treatment of 5HT and drug monoamine oxidase inhibitors at least in the last two weeks. The result of the nicotine dependency test is over 6. without Advanced liver and kidney disease.

Intervention groups

A total of three groups were used in all groups: psychotherapy, behavioral therapy along with the use of bopropion 150 mg twice daily, in the second group with a herbal remedy for reducing and smoking cessation (Apple Health Number 568060 And also patent number 95179) contains four flowering herbs, mountain tea, lavender and green tea with equal proportions, and also in the third group, with chamomile cucumber, which has

been shown to reduce the effects of smoking.

Main outcome variables

Reduction in the intake of smoke and quit smoking and reduce the symptoms of smoking cessation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180725040596N1**

Registration date: **2018-12-07, 1397/09/16**

Registration timing: **prospective**

Last update: **2018-12-07, 1397/09/16**

Update count: **0**

Registration date

2018-12-07, 1397/09/16

Registrant information

Name

Nasir Dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 5162

Email address

dehghan.n@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey effectiveness of Combined Herbal Remedies with Bupropion on cigarette smoking in patients referring to quit cigarette clinic - A Randomized Clinical Trial

Public title
Survey effectiveness of Combined Herbal Remedies with Bupropion on cigarette smoking in patients referring to quit cigarette clinic - A Randomized Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

They have a history of smoking for at least one year The amount of cigarettes per person be more than 10 cigarettes per day The age range is between 20 and 65 years old The person taking the drug does not take a drug from group of drugs for marking the 5HT system The person taking the drug does not take an inhibitor of manovin oxidase, at least in the last two weeks The result of the nicotine dependency test is over than 6 Diagnosis is based on the indication of taking bupropion to help quit smoking

Exclusion criteria:

Do not have advanced liver disease Do not have advanced kidney disease Do not during pregnancy and breastfeeding

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

In this study, the participants are divided into three groups that do not know which group uses combine herbal and herbal remedies in chamomile. Also, the analyst and data monitoring officer from this group of uninformed clients Will remain unaware.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research in School of Medicine, Iran University of Medical Sciences

Street address

13th Floor, Block A, between South Felamak and Zarafshan, Iran-Iran Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.IUMS.FMD.REC.1397.022

Health conditions studied

1

Description of health condition studied

Nicotine dependence

ICD-10 code

F17.2

ICD-10 code description

Nicotine dependence

Primary outcomes

1

Description

Reduce smoking in people with moderate to severe nicotine addiction

Timepoint

For six weeks, visits every two weeks (with an initial visit of a total of 4 turns)

Method of measurement

Checklist and interview with participant

2

Description

Reduce the symptoms of smoking cessation

Timepoint

For six weeks, visits every two weeks (with an initial visit of a total of 4 turns)

Method of measurement

Checklist and interview with participant

Secondary outcomes

1

Description

Reduce Symptoms Caused by Cigarette Smoking

Timepoint

For six weeks, visits every two weeks (with an initial visit of a total of 4 turns)

Method of measurement

Checklist and interview with the participant

Intervention groups

1

Description

Intervention group: Psychotherapy, Behavioral Therapy along with Bopropion 150 mg twice daily plus twice daily (morning and evening) herbal remedies for reducing intake and smoking cessation.

Category

Treatment - Drugs

2

Description

Intervention group: Using twice daily 150 mg bupropion tablet with psychotherapy and behavioral therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Centers for smoking cessation of municipal health houses in District 1

Full name of responsible person

Nasir Dehghan

Street address

Ghods Square, Beginning of Shahid Bahonar Street

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dehghan.n@tak.iums.ac.ir

2

Recruitment center

Name of recruitment center

Centers for smoking cessation of municipal health houses in District 2

Full name of responsible person

Nasir Dehghan

Street address

Sa'atat Abad, Shahid Tehrani Moghadam Square (Pine), West Ceder Blvd, Dr. Qaisar Aminpour Blvd, West Thirteenth Avenue

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3

Recruitment center

Name of recruitment center

Centers for smoking cessation of municipal health houses in District 3

Full name of responsible person

Nasir Dehghan

Street address

Tehran, Shariati Avenue, lower than Hosseiniyeh Ershad

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4

Recruitment center

Name of recruitment center

Tobacco Control Research Center of the Counter-Narcotics Counterfeit Population of Iran

Full name of responsible person

Nasir Dehghan

Street address

ValiAsr Ave.Fathi Shaghaghi Ave. Farahani Pour,Tabriz St.Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nasir Dehghan

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Nasir Dehghan

Position

Social Medical Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nasir Dehghan

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Empty

When the data will become available and for how long

Empty

To whom data/document is available

Empty

Under which criteria data/document could be used

Empty

From where data/document is obtainable

Empty

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

Empty

Comments