Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Nicotine Replacement Therapy (NRT) and Nursing consulting on smoking cessation and Spiro metric indexes of smokers candidate for Coronary Artery Bypass Graft (CABG)

Protocol summary

Summary

Objective: Comparison of Nicotine Replacement Therapy (NRT) and Nursing consulting on smoking cessation and Spiro metric indexes of smokers candidate for Coronary Artery Bypass Graft (CABG) , Study design: Randomized controlled trial, with two intervention groups Sample size: 60 participants, Inclusion Criteria: candidate for CABG, smoker and be able to cooperation with research project, Exclusion Criteria: Unstable medical status and refuse for cooperating in study Interventions: After obtaining informed consent from patients in physician clinic, interviewing and filling out the study questionnaire, Fagersturm questionnaire and offering smoking cessation education pamphlet, patients will be divided to both intervention groups (by blocked randomization). Treatment groups include, Nursing consulting group, which will provide consulting for help participants to quit smoking during study time table by telephone contacts. (3 weeks before till 3 weeks after surgery) The other intervention group consist Nicotine Replacement Therapy (NRT). Participants in this group will be allowed to use nicotine gums in requirement times. Instructions of using NRT gums will be teached them in the first time and also by phone contact. Moreover, they will receive nicotine patches by researcher once a day at the time of hospitalization. Patients' pulmonary indexes will be examined by spirometry devices in two times. (A day before surgery and two weeks after that) during the study, another person instead of researcher will follow level of adherence to cessation by telephone contacts and visits during hospitalization. Researcher will visit patients, teach, guide and consult them during hospitalization. Data will be analyzed by SPSS 16 statistics software, descriptive and analytic tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071518499N1**
Registration date: **2014-10-06, 1393/07/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-06, 1393/07/14

Registrant information

Name

Fatemeh Bakhshi

Name of organization / entity

Nursing and midwifery faculty, Tehran university of medical sciences-

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

f_bakhshi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of medical sciences, School of Nursing and Midwifery

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Nicotine Replacement Therapy (NRT) and Nursing consulting on smoking cessation and Spiro metric indexes of smokers candidate for Coronary Artery Bypass Graft (CABG)

Public title

Effect of Nicotine and Consulting on smoking cessation and pulmonary indexes in patients candidate for heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Age 18 years or more 2. Patients tend to have quit smoking 3. Candidates of CABG surgery 4. Non-emergency CABG surgery 5. Smoking addiction 6. No history of mental disorder or having psychologically Cooperation 7. Not allergic to nicotine patches and gum 8. Ability to properly use of nicotine patches 9. Non-use of other cessation forms 10. Have no Addiction to alcohol and other drugs 11. Not having acute or severe respiratory disorders Exclusion Criteria: 1. Occurrence of unstable medical conditions and inability to continue cooperation in the study. 2. Refuse cooperation in study or continue smoking during the study period 3. Conflict to other postoperative complications in such a way that makes it impossible to continue study participation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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 Tehran University of Medical Sciences.

Street address

Sixth floor, in the corner of Ghods St., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

130/486/93/د

Health conditions studied

1

Description of health condition studied

Smokers Candidate for Coronary artery Bypass Graft surgery (CABG)

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Smoking Cessations

Timepoint

Measurements time intervals: Smoking cessation: It will be monitored according to time table. In the way that, during 3 weeks before and till 3 weeks after surgery which is research time table, we will contact to patients and their families separately 2-3 times a week for examining adherence to cessations.

Method of measurement

For smoking cessation: telephone contacts to patients and their families according to time table

2

Description

Patients' Spirometric Indexes

Timepoint

Spirometric indexes: examinations of patients' pulmonary indexes and function by computerized spirometry test in two times (one day before surgery and 2 weeks after that)

Method of measurement

For spirometric indexes: by spirometry Device

Secondary outcomes

1

Description

demographic data and medical history

Timepoint

at the beginning of study in physician clinic

Method of measurement

by interviewing and questionnaire

Intervention groups

1

Description

In NRT group, at the beginning of participation, researcher will explain instructions and dosage of using nicotine gums for patients and their family. Then we will give patients two boxes of gums till the time of surgery, which contain 30 gums in each box and each gum, provide 2mg nicotine. During hospitalization days which are near one week, we will use nicotine patches. Each patch is for daily use and contains 17.5 mg nicotine. After that on the time of discharge, two other boxes of gums will be given to them for their demands on non-hospitalization days. This dosage has approved by experts of cessation center and physicians. (Since hospitalization and postoperative conditions may cause some limitations for using nicotine gums, it's better to use patches instead, in these days which are better for observing amount of NRT that has been used). We will give participants a phone number for contact to researcher and report their allergic reactions, and other problems which make them unable to cooperate with study and also for extra questions.

Category

Treatment - Drugs

2

Description

In consulting group, intervention will be accomplished by phone-consulting (in 10-15 minutes duration each time) and 3 times a week, in non-hospitalization days. (For hospitalization days consults will do in presence). Consults will be done in organized and scheduled method. At the beginning, researcher will examine patients and their family needs for consulting. After that, in each telephone contacts according to their needs, researcher will explain for them, smoking risk factors, cessation benefits, cessation withdrawal symptoms and ways to encounter with them. Researcher also will assess participants' trends for quit smoking, stresses and problems that they encounter with about quitting, then will try to persuade them for cessation and try to remain on it. Also we will give a phone number to participants for contact researcher if necessary.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Herat Center Hospital

Full name of responsible person

Fateme Bakhshi,MSc student in Medical-Surgical Nursing The Tehran University,Iran

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences Vice chancellor for research

Full name of responsible person

Dr. Masood Yunesian

Street address

Tehran University of Medical Sciences, Sixth floor, in the corner of Ghods St., Keshavarz Blvd.

City

Tehran

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 Vice chancellor for research

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

Tehran University of medical Sciences- School of Nursing and Midwifery

Full name of responsible person

Fateme Bakhshi

Position

Master of Nursing Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Dr. Mirkhani St., (East Nosrat) , Tohid Sq.

City

Tehran

Postal code

1419733171

Phone
+98 35 1620 4053
Fax
+98 21 6690 4252
Email
f_bakhshi@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of medical Sciences- School of Nursing and Midwifery
Full name of responsible person
Dr. Shokooh Varaei
Position
PHD of Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Dr. Mirkhani St., (East Nosrat) , Tohid Sq.
City
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
+98 21 6690 4252
Email
shvaraei@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences- School of Nursing and Midwifery
Full name of responsible person
Fatemeh Bakhshi
Position
Master of Nursing Student
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Dr. Mirkhani St., (East Nosrat) , Tohid Sq.
City
Tehran
Postal code
Phone
+98 35 1629 4953
Fax
Email
f_bakhshi@razi.tums.ac.ir
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