

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of three methods of preparing heavy smokers, quit smokers, non-quitters, under treatment with inhaler salbutamol_atrovent_beclometazone with normal spirometry on respiratory complications after Coronary artery bypass grafting (CABG)

Protocol summary

Summary

The purpose of this study is the prevention of pulmonary complications in 225 heavy smokers with normal spirometry, age 35-65 years with American Society of Anesthesiologists (ASA) (I- II- III) and no respiratory symptoms after Coronary artery bypass grafting (CABG). Patients divided into 3 groups. We strongly recommend stopping smoking eight weeks before surgery to all groups. Group 1, smokers have not been treated but smoked before surgery. Groups 2, smokers have been treated with Salbutamol_Atrovent_Beclometazon 10-14 days before surgery and still have smoked before surgery. Groups 3, smokers have quit smoking for 8 weeks. Inclusion criteria: Heavy smokers (20 pack-year); normal spirometry. Exclusion criteria: Pulmonary complications; History of used bronchodilator medicines; fever; cough; sputum. Finally, in all three groups, the pulmonary complications, fever, cough, sputum production are evaluated in the first and second days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052514359N2**
Registration date: **2014-07-09, 1393/04/18**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-09, 1393/04/18

Registrant information

Name

Vally Imantalab

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 9064

Email address

vimantalab@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2014-12-06, 1393/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three methods of preparing heavy smokers, quit smokers, non-quitters, under treatment with inhaler salbutamol_atrovent_beclometazone with normal spirometry on respiratory complications after Coronary artery bypass grafting (CABG)

Public title

Effect of Salbutamol, Beclometazone nasal spray Atrovent Inhaler on pulmonary complications after Coronary artery bypass grafting (CABG)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 65-35 years old; Heavy smokers; Normal spirometry
Exclusion criteria: Fever; Cough; Sputum

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **225**

Randomization (investigator's opinion)

N/A

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 Guilan university of Medical Sciences

Street address

Namjoo street

City

Rasht

Postal code

4193893345

Approval date

2014-02-22, 1392/12/03

Ethics committee reference number

1920422823

Health conditions studied

1

Description of health condition studied

Pulmonary complications in heavy smokers

ICD-10 code

J95.9

ICD-10 code description

اختلال تنفسی

Primary outcomes

1

Description

cough

Timepoint

first and second days after surgery

Method of measurement

times per minute/question

2

Description

wheezing

Timepoint

first and second days after surgery

Method of measurement

Hearing lung

3

Description

ral

Timepoint

first and second days after surgery

Method of measurement

Hearing lung

4

Description

Time of mechanical ventilation

Timepoint

8 hours after surgery

Method of measurement

curve report

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1) smokers haven't been treated and smoked before surgery

Category

Prevention

2

Description

Intervention 2: smokers have been treated with salbutamol_atrovent _ beclometazon and smoked before surgery.

Category

Prevention

3

Description

Intervention 3: Smokers have quit smoking for 8 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Heshmat Hospital

Full name of responsible person

Vali Imantalab

Street address

Next to the Management and Planning Organization,
15 Khordad street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of
Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid beheshti Highway

City

Rasht

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 Guilan University of
Medical Sciences

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

Guilan University of Medical Sciences

Full name of responsible person

Vali Imantalab

Position

Anesthesiologist/ Assistant Professor

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Guilan University of Medical Sciences

Full name of responsible person

Hedieh Nemati

Position

Medical laboratory Sciences Technician/ Bachelor's
Degree

Other areas of specialty/work

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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