

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of green tea solution gargling on the sore throat, cough and hoarseness after coronary artery bypasses grafting

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of green tea gargling solution on post-extubation cough, hoarseness and sore throat in patients undergone coronary artery bypass surgery. This study is single-blind randomized clinical trial with a sample size of 130 patients undergoing coronary artery bypass surgery. Sampling is convenience and allocation in two groups is random. The intervention group participants will be asked to gargle 30 cc of green tea solution. Patients of the control group gargled 30 cc of distilled water. An hour after extubation, the patients of the intervention group will be asked to gargle 30 cc of green tea and the patients of the control group will be asked to gargle 30 cc of distilled water every 6 hours (up to 24 hours). The sore throat, hoarseness and cough Questionnaire will be also filled out 6, 12, and 24 hours after endotracheal extubation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014043017483N2**

Registration date: **2014-12-06, 1393/09/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-06, 1393/09/15

##### Registrant information

###### Name

Mohammadreza Aryaeefar

###### Name of organization / entity

Neyshabur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 4334 4712

###### Email address

m.aryae2012@gmail.com

###### Recruitment status

**Recruitment complete**

###### Funding source

Mazandaran University of Medical Sciences

###### Expected recruitment start date

2014-05-22, 1393/03/01

###### Expected recruitment end date

2014-07-01, 1393/04/10

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of green tea solution gargling on the sore throat, cough and hoarseness after coronary artery bypasses grafting

###### Public title

The effect of green tea solution gargling on the sore throat, cough and hoarseness after coronary artery bypasses grafting

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criteria included age of 30-70 years, no history of having cold or sore throat during the preceding week, and lack of drug addiction. Exclusion criteria included more than 1 attempt for intubation and more than 30 seconds, Mallampati score of higher than 2, active airway infection, and history of allergy to green tea. Furthermore, patients who kept in the ICU with an endotracheal tube for more than 16 hours, and patients

who were unable to communicate due to different reasons, such as dangerous dysrhythmias, bleeding, loss of consciousness, or any other reason, will be excluded from the study.

#### Age

From **36 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran University of Medical sciences

##### Street address

Imam Squar, Joybar 3way, Start of valiye asr highway,  
Mazandaran University of Medical Sciences

##### City

Sari

##### Postal code

#### Approval date

2014-07-09, 1393/04/18

#### Ethics committee reference number

1393,18,04

## Health conditions studied

### 1

#### Description of health condition studied

Sore throat Cough

#### ICD-10 code

R05, J02

#### ICD-10 code description

Cough , acute sore throat

## Primary outcomes

### 1

#### Description

Sore throat

#### Timepoint

0, 6 ,12 and 24 hour after endotracheal extubation

#### Method of measurement

Visual Analogue Scale (VAS)

### 2

#### Description

cough

#### Timepoint

0, 6 ,12 and 24 hour after endotracheal extubation

#### Method of measurement

4 Point Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group participants were asked to gargle 30 cc of green tea solution every 6 hours (up to 24 hours) .

#### Category

Prevention

### 2

#### Description

The control group participants were asked to gargle 30 cc of distilled water every 6 hours (up to 24 hours) .

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mazandaran Heart Center

##### Full name of responsible person

Dr Aria Soleimani

##### Street address

Artesh Blv. Mazandaran Heart Center, Sari, Iran.

##### City

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Council of Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Ahmad Ali Enayati

**Street address**

Moalem Squar, Research Council of Mazandaran University of Medical Sciences.

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Council of Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hedayat Jafari

**Position**

Faculty member

**Other areas of specialty/work****Street address**

Amir Mazandarani Blv, Nasibeh Faculty of Nursing and Midwifery

**City**

Sari

**Postal code****Phone**

+98 15 1326 1245

**Fax****Email**

hedayat2003@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hedayat Jafari

**Position**

PhD in Nursing

**Other areas of specialty/work****Street address**

Amir Mazandarani Blv, Nasibeh Faculty of Nursing and Midwifery

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Aryaeefar

**Position**

MSc student

**Other areas of specialty/work****Street address**

Amir Mazandarani Blv, Nasibeh Faculty of Nursing and Midwifery

**City**

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**Postal code****Phone**

+98 15 1326 1245

**Fax****Email**

m.aryae2012@gmail.com

**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*