

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of honey lemon solution on the improvement of sore throat after intubation among candidates for general anesthesia

#### Protocol summary

##### Study aim

Evaluation of the effect of honey and lemon juice solution on postoperative sore throat

##### Design

This study is a single blind clinical trial. In this study, 86 patients will be randomly divided into intervention and control groups.

##### Settings and conduct

This study will be conducted at the 22 Bahman hospital in Neyshabur. Patients will enter the study after checking the inclusion criteria and informed consent. Then Demographic information and anesthetic information questionnaire is completed by the Collaborative nurse. In this study, patients are randomly divided into intervention and control groups. This study is single blind in which the nurse collecting information from the patients has no information about the groups patients are belonged to.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having Consent form, being satisfied the surgeon for swallowing of honey lemon juice solution , Candidate for general anesthesia and endotracheal intubation, The operating time is less than 6 hours, Age between 15 to 60, Ability to communicate and answer questions. Exclusion criteria: sensitivity to honey and lemon juice solution, having diabetes

##### Intervention groups

In the intervention group one hour after surgery and before intervention questionnaires about sore throat, cough and hoarseness will be completed. Then, after 6 hours of surgery, the patient will receive 30 cc of lemon juice and honey, Then After 12 and 24 hours after the intervention, the above mentioned questionnaires are completed. In the control group, normal saline will be used as a placebo.

##### Main outcome variables

In this study, postoperative sore throat, cough and hoarseness as a result of the study will be evaluated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150511022218N4**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

##### Registration date

2018-08-19, 1397/05/28

##### Registrant information

##### Name

Vahid Moeini Ghamchini

##### Name of organization / entity

Neyshabour University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4261 4062

##### Email address

v.moinighamchini@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-16, 1397/04/25

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of honey lemon solution on the improvement of sore throat after intubation among candidates for general anesthesia

## Public title

The effect of honey lemon solution on postoperative sore throat

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having Consent form Surgeon satisfaction for patient to drink honey and lemon juice solution Candidate for general anesthesia and endotracheal intubation The operating time less than 6 hours Age between 15 to 60 years old Ability to communicate and answer the questions

### Exclusion criteria:

Being allergic to honey and lemon juice solution Having diabetes

## Age

From **15 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **86**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, sampling is easy and accessible. Patients are randomly dividing into intervention and control groups. It should be noted that the study samples are randomly divided into two groups through block randomization.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This study is a single blind clinical trial in which the Nurse that helps researchers to fill out the questionnaire won't know the group patients are belong to.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics Committee of Neyshabur University of Medical Sciences

#### Street address

Neyshabur University of Medical Sciences

#### City

Neyshabur

#### Province

Razavi Khorasan

#### Postal code

6623451124

#### Approval date

2018-05-14, 1397/02/24

#### Ethics committee reference number

IR.NUMS.REC.1397.006

## Health conditions studied

### 1

#### Description of health condition studied

postoperative sore throat

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

sore throat

#### Timepoint

One hour after surgery and before intervention, 12 and 24 hour after intervention

#### Method of measurement

Visual Analogue Scale( VAS )

## Secondary outcomes

### 1

#### Description

Cough

#### Timepoint

One hour after surgery and before intervention, 12 and 24 hour after intervention

#### Method of measurement

questionnaire

### 2

#### Description

Hoarseness

#### Timepoint

One hour after surgery and before intervention, 12 and 24 hour after intervention

#### Method of measurement

questionnaire

## Intervention groups

## 1

### Description

Intervention group: In the intervention group one hour after surgery and before intervention questionnaires about sore throat, cough and hoarseness will be completed. Then, after 6 hours of surgery, the patient will receive 30 cc of lemon juice and honey. The reconstituted solution will be provided to patients with clear containers. Prescribed solution will also be given to the patients 2 and 4 hours after the first dose. In general, each patient will use the solution mentioned 3 times. The Honey was produced by Khomein Company with a health license number 15/11066. The lemon juice was produced by the Yek&Yek company with a health license number 36/10374. Then After 12 and 24 hours after the intervention, the above mentioned questionnaires are completed again.

### Category

Prevention

## 2

### Description

Control group: In the Control group one hour after surgery questionnaires about sore throat, cough and hoarseness will be completed. In the control group, patients at the same time with the intervention group will use saline as placebo. Then After 12 and 24 hours after the intervention, the above mentioned questionnaires are completed again.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

22 Bahman Neyshabur Hospital

#### Full name of responsible person

mohammadreza Aryaeefar

#### Street address

Neyshabur University of Medical Sciences

#### City

neyshabur

#### Province

Razavi Khorasan

#### Postal code

6623451124

#### Phone

+98 51 4334 4711

#### Email

m.aryaee2012@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Neyshabour University of Medical Sciences

#### Full name of responsible person

mohammadreza Aryaeefar

#### Street address

Neyshabur University of Medical Sciences

#### City

Neyshabur

#### Province

Razavi Khorasan

#### Postal code

6623451124

#### Phone

+98 51 4334 4711

#### Email

m.aryaee2012@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Neyshabour 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

Neyshabour University of Medical Sciences

#### Full name of responsible person

Mohammad Reza Aryaeefar

#### Position

Faculty member

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

Neyshabur University of Medical Sciences

#### City

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Neyshabour University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Aryaeefar

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Neyshabur University of Medical Sciences

**City**

Neyshabur

**Province**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Neyshabour University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Aryaeefar

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Neyshabur University of Medical Sciences

**City**

Neyshabur

**Province**

Razavi Khorasan

**Postal code**

6623451124

**Phone**

+98 51 4334 4711

**Email**

m.aryae2012@gmail.com

## 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**

There is no more information.

**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**

No - There is not 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