

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### An evaluation of the efficacy of different doses of licorice gargling for attenuating postoperative sore throat after tracheal intubation

#### Protocol summary

##### Summary

This study was designed to evaluate the efficacy of different doses of licorice on postoperative sore throat and postextubation cough. Patients with ages between 18 and 65, undergoing any operation other than head and neck surgery with general anesthesia for their first time were included to the study, and those with any change in the method or frequency of anesthesia, intubation or extubation were excluded. In this double blind clinical trial, 144 patients were randomly allocated to four groups of 36 patients to gargle doses of zero (control), 0.25, 0.5, and one gram of licorice in 30 milliliter of water before general anesthesia and operation. Then sore throat in rest and swallowing position in zero, two, four, and 24 hours postoperation, and postextubation cough, were evaluated and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201411115362N21**

Registration date: **2015-01-19, 1393/10/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-19, 1393/10/29

##### Registrant information

###### Name

Mohammadreza Safavi

###### Name of organization / entity

Anesthesiology and Critical Care Research Center,  
Isfahan University of Medical Sciences, Isfahan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1273 2659

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##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-01-01, 1391/10/12

##### Expected recruitment end date

2014-10-31, 1393/08/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

An evaluation of the efficacy of different doses of licorice gargling for attenuating postoperative sore throat after tracheal intubation

##### Public title

Licorice gargling to decrease sore throat after surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients underwent any operation other than head and neck surgery under general anesthesia; aged between 18 and 65 years; with American Society of Anesthesia (ASA) physical status I and II; no NSAID use; no perioperative corticosteroid intake (from 24 hours before operation); no allergy or intolerance to licorice; no upper respiratory tract infection; without mallampati grade more than two. Exclusion criteria: Any change in anesthetic technique; requiring more than one attempt for intubation; not being extubated at the end of the

surgery; re-intubation within the study period.

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **144**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Hezarjarib Street

##### City

Isfahan

##### Postal code

#### Approval date

2012-06-13, 1391/03/24

#### Ethics committee reference number

391132

## Health conditions studied

### 1

#### Description of health condition studied

Postoperative Sore Throat (POST)

#### ICD-10 code

R07.0

#### ICD-10 code description

Pain in throat

### 2

#### Description of health condition studied

Postextubation Cough

#### ICD-10 code

R05

#### ICD-10 code description

Cough

## Primary outcomes

### 1

#### Description

Postoperative Sore Throat

#### Timepoint

0, 2, 4, and 24 hours after operation

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Postextubation Cough

#### Timepoint

after extubation

#### Method of measurement

Observation

### 2

#### Description

Patient Satisfaction

#### Timepoint

24 hours after operation

#### Method of measurement

Likert form asked from patient (very satisfied, satisfied, no opinion, dissatisfied, very dissatisfied)

## Intervention groups

### 1

#### Description

Group A: Licorice (Gargling, 0.25 gram Licorice in 30 ml of water, 5min before operation, for 30 seconds)

#### Category

Prevention

### 2

#### Description

Group B: Licorice (Gargling, 0.5 gram Licorice in 30 ml of water, 5min before operation, for 30 seconds)

#### Category

Treatment - Drugs

### 3

#### Description

Group C: Licorice (Gargling, 1 gram Licorice in 30 ml of water, 5min before operation, for 30 seconds)

#### Category

Treatment - Drugs

#### 4

##### **Description**

Group D (Control group): Placebo (Gargling, only 30 ml of water, 5min before operation, for 30 seconds)

##### **Category**

Treatment - Drugs

#### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Ayatollah Kashani Hospital

###### **Full name of responsible person**

Dr. Azim Honarmand

###### **Street address**

Ayatollah Kashani Hospital, Ayatollah Kashani Street,  
Isfahan

###### **City**

Isfahan

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Isfahan University of Medical Sciences

###### **Full name of responsible person**

Dr. Mansur Siavash

###### **Street address**

Hezarjarib Street

###### **City**

Isfahan

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

###### **Full name of responsible person**

Dr.Mohammadreza Safavi

##### **Position**

Associat Professor

##### **Other areas of specialty/work**

##### **Street address**

Hezarjarib Street

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##### **Web page address**

#### **Person responsible for scientific inquiries**

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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*