

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of frequency of sore throat after jaw surgery with and without pharyngeal packing

#### Protocol summary

2021-08-25, 1400/06/03

#### Study aim

Comparison of frequency of sore throat after jaw surgery with and without pharyngeal packing

#### Design

The study is a single-blind clinical trial on 60 patients aged 18 - 40 years old with mallampati class of I-II who are candidates for jaw surgery. Convenience sampling will be used and randomization will be done using random numbers table.

#### Settings and conduct

The study will be done in Shafa and Bahnoar hospital in Kerman. The study is a single-blind clinical trial. Patients are not aware of the group they are assigned to.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates of jaw surgery; Mallampati class of II - I. Exclusion: Lack of participation consent; Prolonged laryngoscopy (more than 15 seconds or more than once); History of a sore throat before the surgery

#### Intervention groups

Intervention group: pharyngeal packing with a gauze soaked with 10cc normal saline solution. Control group: no packing.

#### Main outcome variables

Sore throat severity and related symptoms (Odynophagia, cough, nausea, vomiting)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210730052019N1**

Registration date: **2021-08-25, 1400/06/03**

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

Last update: **2021-08-25, 1400/06/03**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Mehran Ilaghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3251 7779

##### Email address

mehran-ilaghi@kmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2021-08-23, 1400/06/01

#### Expected recruitment end date

2021-09-22, 1400/06/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of frequency of sore throat after jaw surgery with and without pharyngeal packing

#### Public title

Effect of pharyngeal packing on sore throat after jaw surgery

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Candidates of jaw surgery Mallampati class of II - I

##### Exclusion criteria:

Lack of participation consent Prolonged laryngoscopy

(more than 15 seconds or more than once) History of sore throat before the surgery

#### Age

From **18 years** old to **40 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Since we need an equal number of participants in each group, we will use the block randomization method using Random Allocation Software. The software will randomly assign 60 patient codes to either intervention or control group. In order of entering the study and recruit, patients will be assigned to codes 1 to 60 and regarding the output of the software, the assigned group of the participant will be determined.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The study is a single-blind randomized clinical trial in which the patients are not aware of the group they are assigned to. Caretakers, investigators, and data analyst are aware of the groups.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

##### Street address

Haftbagh-Alavi highway, Kerman University of medical Sciences

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

#### Approval date

2021-08-15, 1400/05/24

#### Ethics committee reference number

IR.KMU.AH.REC.1400.096

## Health conditions studied

### 1

#### Description of health condition studied

anesthesia , Jaw surgery

#### ICD-10 code

M27.9

#### ICD-10 code description

Disease of jaws, unspecified

## Primary outcomes

### 1

#### Description

Severity of sore throat

#### Timepoint

2, 6, 12, 24 hours after surgery

#### Method of measurement

visual analogue scale

### 2

#### Description

Nausea

#### Timepoint

2, 6, 12, 24 hours after surgery

#### Method of measurement

Data gathering sheet (Subjective interview with patient)

### 3

#### Description

Vomitting

#### Timepoint

2, 6, 12, 24 hours after surgery

#### Method of measurement

Data gathering sheet (Subjective interview with patient)

### 4

#### Description

Cough

#### Timepoint

2, 6, 12, 24 hours after surgery

#### Method of measurement

Data gathering sheet (Subjective interview with patient)

### 5

#### Description

Odynophagia

#### Timepoint

2, 6, 12, 24 hours after surgery

#### Method of measurement

Data gathering sheet (Subjective interview with patient)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In intervention group a gauze soaked with 10 cc normal saline solution for pharyngeal packing.

#### Category

Prevention

### 2

#### Description

Control group: Despite the intervention group, in control group no pharyngeal packing will be used.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shafa hospital

##### Full name of responsible person

Roohollah Movahedinia

##### Street address

Shafa street, Shafa hospital

##### City

Kerman

##### Province

Kerman

##### Postal code

۷۶۱۸۷۵۱۱۵۱

##### Phone

+98 34 3211 5780

##### Email

shafahospital@kmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Bahonar Hospital

##### Full name of responsible person

Roohollah Movahedi

##### Street address

Valiasr crossroad, Bahonar Hospital

##### City

Kerman

##### Province

Kerman

##### Postal code

7613747181

##### Phone

+98 34 3223 5011

##### Email

Bh.hospital@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Davood Kalantar

##### Street address

Haftbagh alavi highway, Kerman University of Medical Sciences

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 5700

##### Email

vcr@kmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kerman University of Medical Sciences

#### Proportion provided by this source

0

#### 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

Kerman University of Medical Sciences

##### Full name of responsible person

Roohollah Movahedinia

##### Position

Associate Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Shafa street, shafa hospital

##### City

kerman

##### Province

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##### Postal code

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
Associate Professor  
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**Other areas of specialty/work**  
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**Province**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Roohollah Movahedinia  
**Position**

Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available