

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

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Phone

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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

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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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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