

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of diphenhydramin hydrochloride gargling in the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

Protocol summary

Study aim

Determining the effect of diphenhydramin hydrochloride gargling in the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

Design

Clinical trials with control group, phase 2, with parallel groups, blinding were performed on 83 patients.

Settings and conduct

This project is being done at Khatam Ophthalmology Hospital and in patients undergoing cataract surgery.

Participants/Inclusion and exclusion criteria

Patients undergoing cataract surgery with surgery less than 60 minutes

Intervention groups

Before using laryngeal mask in control group, gargle method was used with 20 cc normal saline . The intervention group used 8 mg diphenhydramine equivalent to 20 mg in 12 cc normal saline.

Main outcome variables

Age, sex, group therapy, degree of sore throat, intensity of sore throat, size of laryngeal mask, duration of operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170429033680N9**

Registration date: **2018-10-01, 1397/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-01, 1397/07/09**

Update count: **0**

Registration date

2018-10-01, 1397/07/09

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2631

Email address

golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-02-26, 1392/12/07

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of diphenhydramin hydrochloride gargling in the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

Public title

The effect of diphenhydramin hydrochloride gargling in the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing cataract surgery with surgery less than 60 minutes Age over 15 years

Exclusion criteria:
Surgery for more than two hours Consumption of NSAIDs in the last two days Consumption of smoking and Opiate Sensitization Laryngeal mask insertion problem Diseases such as asthma and pharyngitis Obesity too Muscular neuromuscular problems Mental problems

Age
From **15 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **83**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and the person who injects the drug do not aware of the type of drug

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Department of Anesthesiology, Imam Reza Hospital, Square Taghiabad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2014-02-26, 1392/12/07

Ethics committee reference number

911228

Health conditions studied

1

Description of health condition studied

cataract surgery

ICD-10 code

H59.0

ICD-10 code description

Keratopathy (bullous aphakic) following cataract surgery

Primary outcomes

1

Description

Severe sore throat

Timepoint

after surgery

Method of measurement

interview

2

Description

Pain of Sore throat

Timepoint

after surgery

Method of measurement

VAS Scale

Secondary outcomes

1

Description

Laryngeal Mask Size

Timepoint

before surgery

Method of measurement

standard number

Intervention groups

1

Description

Intervention group: Diphen Hydramine 8cc Cylinder Spool 20 mg in 12 cc normal saline before applying mask

Category

Prevention

2

Description

Control group: Gargle with 20 cc normal saline before applying mask

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mohsen Saber Moghaddam

Street address

Department of Anesthesiology, Ghaem Hospital,
Square Taghiabad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3852 5209

Email

SaberMoghaddamM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

International Office Administration Center(Qoreishi
Building) ; Daneshgah St.,

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Saber Moghaddam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ghaem Hospital, Taghiabad Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3852 5209

Email

sabermoghadamm@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Saber Moghaddam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ghaem Hospital, Taghiabad Square

City

Mashad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 518525209

Email

sabermoghadamm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Saber Moghaddam

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ghaem Hospital, Taghiabad Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3852 5209

Email

sabermoghaddamm@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data file

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Statistical analyzes are permitted in overview articles on delivered data

From where data/document is obtainable

Send an email to sabermoghaddamm@mums.ac.ir

What processes are involved for a request to access data/document

6 months after publication

Comments