

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Investigation of the effect of licophar tablet on reduction of the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

#### Protocol summary

##### Study aim

Investigation of the effect of licophar tablet on reduction of the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

##### Design

clinical trial with control and parallel groups, single blind, randomized.

##### Settings and conduct

This study will be conducted in Khatam Eye Hospital in Mashhad on 160 patients undergoing cataract surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients undergoing cataract surgery with operating time of less than 60 minutes. Exclusion criteria: use of NSAIDs in the past 2 days, use of drugs and cigarettes, upper airway problem (obesity, patients with ASA above 2, swollen tonsils), asthma, pharyngitis, neuromuscular problems (such as Myasthenia gravis - ALS), mental health problems in a way that the intended outcome cannot be evaluated in the patient, excessive obesity (BMI > 35), diabetes, hypertension, being in pregnancy or lactation.

##### Intervention groups

Intervention group: Licophar Lozenge (produced by Goldaru company) will be given to patients half an hour before surgery. Control group: No drug will be used.

##### Main outcome variables

Rate of sore throat based on visual analog scale (VAS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170415033428N4**

Registration date: **2020-03-15, 1398/12/25**

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

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

##### Registration date

2020-03-15, 1398/12/25

##### Registrant information

###### Name

Elham Bakhtiari

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3727 3943

###### Email address

bakhtiarie@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-02-17, 1398/11/28

##### Expected recruitment end date

2020-07-18, 1399/04/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of the effect of licophar tablet on reduction of the sore throat of patients undergoing cataract surgery after insertion of laryngeal mask airway

##### Public title

Investigation of the effect of licophar tablet on sore throat of patients undergoing cataract surgery after

insertion of laryngeal mask airway

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

patients undergoing cataract surgery with operating time of less than 60 minutes

##### **Exclusion criteria:**

use of NSAIDS in the past 2 days use of drugs and cigarettes upper airway problem (obesity, patients with ASA above 2, swollen tonsils) asthma pharyngitis neuromuscular problems (such as Myasthenia gravis - ALS) mental health problems in a way that the intended outcome cannot be evaluated in the patient excessive obesity (BMI > 35) diabetes, hypertension, being in pregnancy or lactation

#### **Age**

From **20 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Outcome assessor

#### **Sample size**

Target sample size: **160**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Simple randomization will be carried out using table of random numbers available at 'www.randomization.com' website where the produced numbers are placed in sealed envelopes assigning each patient to one of the two groups.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

The evaluator and analyst will be unaware of the control and intervention groups.

#### **Placebo**

Not 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**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9138813944

#### **Approval date**

2019-11-19, 1398/08/28

#### **Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1398.707

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

cataract

##### **ICD-10 code**

H59.0

##### **ICD-10 code description**

Disorders of the eye following cataract surgery

### **Primary outcomes**

#### **1**

##### **Description**

rate of sore throat

##### **Timepoint**

at 3,6,12 and 24 hours after operation

##### **Method of measurement**

based on visual analog scale (VAS)

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Licophar Lozenge (produced by Goldaru company) will be given to patients half an hour before surgery.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Control group: No drug will be used.

##### **Category**

N/A

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Khatam eye hospital

**Full name of responsible person**

Mohammad Alipour

**Street address**

Khatam eye hospital, Gharani 31, Gharani Blv

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177899191

**Phone**

+98 51 3728 1401

**Email**

Alipourm@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**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

**City**

Mashhad

**Province**

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**Postal code**

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**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**

Mohammad Alipour

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3852 5209

**Email**

alipourm@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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Mohammad Alipour

**Position**

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**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**

Yes - There is 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**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data can be shared after patients are made unidentifiable.

**When the data will become available and for how long**

Data can be accessible 6 months after results are published.

**To whom data/document is available**

Data will be available for researchers in universities and other scientific institutes

**Under which criteria data/document could be used**

Carrying out analysis on data is permitted.

**From where data/document is obtainable**

Data can be accessible through sending an email to the corresponding author

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

After sending a request email to the corresponding author, data will be sent in 1 month.

**Comments**