

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)

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+98 51 3727 3943

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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

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9177899191

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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

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

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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

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Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

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

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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