

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparative evaluation of the efficacy of three different doses of atracurium on Laryngeal Mask Airway insertion conditions in patients undergoing phacoemulsification surgery

Protocol summary

Study aim

Determination of the effectiveness of three different doses of atracurium on the conditions of laryngeal mask airway insertion in patients undergoing cataract surgery by phacoemulsification "

Design

Double-blind, randomized clinical trial using random computer numbers with parallel groups designed for 120 patients

Settings and conduct

Using three doses of atracurium in three groups of patients and comparing their effect on facilitating the use of the laryngeal mask (LMA) in cataract surgery by phacoemulsification in Faiz Hospital in Isfahan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 30-80 years undergoing surgery by phacoemulsification with general anesthesia. Non-inclusion criteria: Poor mouth opening Pharyngeal pathology Laryngeal pathology Pulmonary diseases Risk of aspiration (full stomach, gastroesophageal reflux disease, pregnancy) History of allergy to any anesthetic drugs High airway resistance

Intervention groups

The first group received atracurium 0.2mg / kg The second group received atracurium 0.4 mg / kg The third group received atracurium 0.6 mg / kg

Main outcome variables

Time of insertion of Laryngeal mask airway

Last update: **2018-10-29, 1397/08/07**

Update count: **0**

Registration date

2018-10-29, 1397/08/07

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

2018-03-11, 1396/12/20

Scientific title

Comparative evaluation of the efficacy of three different doses of atracurium on Laryngeal Mask Airway insertion conditions in patients undergoing phacoemulsification surgery

Public title

Effect of atracurium on Laryngeal Mask Airway insertion phacoemulsification

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N5**

Registration date: **2018-10-29, 1397/08/07**

Registration timing: **retrospective**

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing cataract surgery by phacoemulsification 30 -50 years old ASA 1 or 2

Exclusion criteria:

Poor mouth opening Pharyngeal pathology Laryngeal pathology Pulmonary diseases Risk of aspiration (full stomach, gastroesophageal reflux disease, pregnancy) History of allergy to any anesthetic drugs" High airway resistance

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

An independent researcher creates random assignment cards using random computer numbers. Based on randomized sequencing, patients are enrolled in the study in three groups Random allocation cards are kept in an inaccessible location, in the end of the study these cards will be accessible for data analyzer

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were unaware of the dosage of the drug, and also to prevent blindness, the drugs were prepared by an anesthetist who was not during the study in the same syringes and encoded and given to the presenter for injection. The data was also collected by the project manager who was unaware of the dose of injectable drugs.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical

Sciences

Street address

Hezarjarib Blvd, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

Ir.mui.rec.1396.3.925

Health conditions studied

1

Description of health condition studied

Airway management by using laryngeal airway

ICD-10 code

Y55.1

ICD-10 code description

Skeletal muscle relaxants [neuromuscular blocking agents]

Primary outcomes

1

Description

Atracurium dosage

Timepoint

At the time of induction of anesthesia

Method of measurement

Milligram

2

Description

Ease of insertion of LMA

Timepoint

once

Method of measurement

The first attempt was made in 15 seconds and without the displacement = Easy, LMA In the first attempt needed more than 15 seconds, and need to LMA displacement = a bit of trouble, Need more than once trying to insertion of LMA, Need more than 30 seconds time And need to multiple LMA moves = quite difficult)

3

Description

Air leakage around LMA

Timepoint

once

Method of measurement

Yes = audible sound At the time of patient manual ventilation. No = Lack of sound at the time of patient manual ventilation.

4

Description

The number of attempts to insertion of laryngeal mask airway

Timepoint

During insertion of laryngeal airway mask

Method of measurement

The number

Secondary outcomes

1

Description

Move the limbs

Timepoint

During laryngeal mask insertion

Method of measurement

View and score based on Score 0 to 3

2

Description

Laryngospasm

Timepoint

During laryngeal mask insertion

Method of measurement

View and score based on Score 0 to 3

3

Description

Gagging

Timepoint

During laryngeal mask insertion

Method of measurement

View and score based on Score 0 to 3

4

Description

Cough

Timepoint

During insertion

Method of measurement

View and score based on Score 0 to 3

Intervention groups

1

Description

Intervention group: In this group after induction of anesthesia patients, receives atracurium at a dose of 0.2 mg/kg

Category

Treatment - Drugs

2

Description

Intervention group: In this group after induction of

anesthesia patients, receives atracurium at a dose of 0.4mg/kg

Category

Treatment - Drugs

3

Description

Control group: In this group after induction of anesthesia patients, receives atracurium at a dose of 0.6 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faiz Hospital

Full name of responsible person

Hamidreza Shetabi

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Modares St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoy

Street address

Vice chancellor of research and technology of university.Isfahan University of Medical Sciences.Hezarjarib St

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research@mui.ac.ir

Web page address

<https://reseach.mui.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Assistant Proffessor

Latest degree

Specialist

Other areas of specialty/work

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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