

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of intravenous Dexamethasone on prevention of complications of laryngeal mask airway (LMA) in inguinal region surgeries

Protocol summary

Study aim

Determination of the effect of intravenous Dexamethasone in the prevention of Laryngeal Mask Airway(LMA) complications including nausea&vomiting,sore throat,cough& chills in inguinal surgeries.

Design

Clinical trial with control&intervention groups,with parallel groups,double blind,randomized,phase3 on140 patients.Patients will be assigned between 2groups using a random quadruple block method.

Settings and conduct

In this study,a sample of 140 patients who are candidate for inguinal region surgery and will have general anesthesia with classical LMA in Imam Reza, Imam Khomeini and Fatemi hospitals in Ardabil, is selected.Patients will be assigned between 2groups using a random quadruple block method and It is double-blind. Except for the executor of the project, the rest, including patients and clinical caregivers and evaluators and analyzers, will be unaware of the type and amount of medicine. Group1:After establishing the airway,Dexamethasone 8mg/IV/stat will be injected. Group2:After establishing the airway,Normal Saline 2cc/IV/stat will be injected. After the operation,in recovery and also 2&4 hours after the operation,patients are examined for complications ,and recorded.Finally,they will be analyzed.

Participants/Inclusion and exclusion criteria

Patients who are candidate for inguinal surgery and will have general anesthesia with classical LMA are selected. If the patient is not satisfied or American Society of Anesthesiologists greater than or equal to3, he/she will not enter the study.

Intervention groups

Intervention group(70 patients) will have general anesthesia with LMA.After establishing the airway,Dexamethasone 8mg/IV/stat will be injected. Control group(70 patients) will have general anesthesia

with LMA. After establishing the airway,Normal Saline 2cc/IV/stat will be injected.

Main outcome variables

Nausea&vomiting;Cough;Sore throat;Chills;Odynophagia;Dyspnea;Epigastric pain

General information

Reason for update

Acronym

LMA=Laryngeal Mask Airway, ASA=American Society of Anesthesiologists

IRCT registration information

IRCT registration number: **IRCT20200730048255N1**
Registration date: **2020-09-05, 1399/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

Name

Ahmad Ghazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3324 8888

Email address

dr.ghaziahmad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-24, 1399/06/03

Expected recruitment end date

2020-10-24, 1399/08/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of intravenous Dexamethasone on prevention of complications of laryngeal mask airway (LMA) in inguinal region surgeries

Public title
Effect of intravenous Dexamethasone on prevention of complications of laryngeal mask airway in inguinal region surgeries

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients who are candidate for inguinal region surgery (hernia and unilateral varicocele repair) and undergo general anesthesia using classical LMA is selected.
Exclusion criteria:
 Dissatisfaction of eligible patients to participate in the study American Society of Anesthesiologists ≥ 3

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
. In terms of random allocation, patients will be assigned between two groups using a random quadruple blocks method. Thus, we will create blocks A, B, C and D and it will be randomly assigned to the relevant groups (Dexamethasone group and control group). The blocks are pre-prepared and randomly assigned to the control group and the Dexamethasone group. Except for the executor of the project, the rest, including patients and clinical caregivers and evaluators and analyzers, will be unaware of the type and amount of medicine.

Blinding (investigator's opinion)
Double blinded

Blinding description
In terms of blinding, Dexamethasone and Normal Saline will be given to the anesthesia technician in ready-made syringes and will be injected in order of quadruple blocks. In terms of outcomes measurement, the assessor will measure the studied variables and he will be

unaware of the classification of the group receiving Dexamethasone or Normal Saline. Except for the executor of the project, the rest, including patients and clinical caregivers and evaluators and analyzers, will be unaware of the type and amount of medicine.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Dadghostari square

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.ARUMS.REC.1399.232

Health conditions studied

1

Description of health condition studied

Inguinal region surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

After extubation, postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Nausea and Vomiting score: score 1: no nausea and vomiting; score 2: nausea; score 3: 1 or 2 times nausea and vomiting; score 4: nausea and vomiting more than 2 times

2

Description

Cough

Timepoint

Postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Asking the patient

3

Description

Sore throat

Timepoint

Postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Asking the patient

4

Description

Chills

Timepoint

Postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Chills score: score 0: No chills; score 1: peripheral vasoconstriction and peripheral cyanosis without specific cause but without visible muscle contraction; score 2: visible contraction limited to one muscle group; score 3: visible contraction in more than one muscle group; score 4: Clear muscle activity throughout the body

5

Description

Odynophagia

Timepoint

Postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Asking the patient

6

Description

Dyspnea

Timepoint

Postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Asking the patient

7

Description

Epigastric pain

Timepoint

Postoperative recovery, 2 and 4 hours after surgery

Method of measurement

Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (70 patients): This group will have general anesthesia with LMA. After establishing the airway, Dexamethasone 8 mg / IV / stat will be injected.

Category

Prevention

2

Description

Control group (70 patients): This group will have general anesthesia with LMA. After establishing the airway, Normal Saline 2cc / IV / stat will be injected.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Ahmad Ghazi

Street address

Near to Islamic Azad University, Basij square

City

Ardabil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3373 3086

Email

dr.ghaziahmad@gmail.com

2

Recruitment center

Name of recruitment center

Dr. Fatemi Hospital

Full name of responsible person

Dr. Masood Entezariasl

Street address

Imam Khomeini street, Sarein Station

City

Ardabil

Province

Ardabil

Postal code

5614733775

Phone

+98 45 3323 2520

Email

masoodentezari2003@yahoo.com

3

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Arezoo Fekrat

Street address

Shahidan Noei Aghdam street, Ataei street

City

Ardabil

Province

Ardabil

Postal code

5619647531

Phone

+98 45 3325 1401

Email

arezoo.fekrat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Farhad Pourfarzi

Street address

Deputy of researches and technology, Ardabil
University of Medical Sciences, Dadghostari square

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3326 2925

Email

F.pourfarzi@arums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Arezoo Fekrat

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Malata Restaurant, the beginning of the lane of
Karshenasan, Keshavarzi Square

City

Ardabil

Province

Ardabil

Postal code

5615861364

Phone

+98 45 3371 0774

Email

arezoo.fekrat@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Ahmad Ghazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Reza Hospital,

City

Ardabil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3373 3086

Email

dr.ghaziahmad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Ahmad Ghazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Reza Hospital,

City

Ardabil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3373 3086

Email

dr.ghaziahmad@gmail.com

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