Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intravenous hydrocortisone in preventing post operative sore throat followed by using laryngeal mask airway in patients undergoing urogenital surgeries

Protocol summary

Summary

Post-operative sore throat is one of the unpleasant side effects due to air way management method durig anesthesia. The aim of this study is to evaluate the effect of intravenous hydrocortisone to preventing post operative sore throat followed by using laryngeal mask airway during urogenital surgery. To do this 60 patients who undergoing urogenital surgery randomly divided to 2 groups (each group n=30). First group recieved 100 mg of intravenous hydrocortisone and second (control) group recieved placebo with the same volume five minutes before anesthesia induction. At the end of the operation and after LMAs removal, patients will be asked about having sore throat, hours 2, 4 and 24 after operation. Sore throat degree will be measured using a four score rating scale by an anesthesiologist who will be unaware of the type of the solution injected before operation. Inclusion Criteria: Elective urogenital surgery, ASA physical status class I-II Exclusion Criteria: Patients refuse to participate into study, Upper respiratory tract abnormalities or infection, sore throat, abdominal surgery, first unsuccessful LMA insertion, patients with full stomach, emergency conditions, pregnancy and smoking. To compare the mean of the normal quantity variables t-test and to compare the abnormal variables Mann-Whitney test were used. Qualitive variables were compared in both groups using Fisher's exact test. Analyses were done using SPSS 15.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104094005N3**
Registration date: **2011-06-12, 1390/03/22**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-06-12, 1390/03/22

Registrant information

Name
Khosro Kolahdouzan
Name of organization / entity
Faculty of Paramedical Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Email address
kolahdozank@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2011-03-16, 1389/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous hydrocortisone in preventing post operative sore throat followed by using laryngeal mask airway in patients undergoing urogenital surgeries

Public title
Effect of intravenous hydrocortisone in preventing post operative sore throat
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: Elective urogenital surgery, ASA physical status class I-II Exclusion Criteria: Patients refuse to participate into study, Upper respiratory tract abnormalities or infection, sore throat, abdominal surgery, first unsuccessful LMA insertion, patients with full stomach, emergency conditions, pregnancy and smoking.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Daneshghah Street
City
Tabriz
Postal code
Approval date
2009-07-16, 1388/04/25
Ethics committee reference number
1325

Health conditions studied

1

Description of health condition studied
Sore throat
ICD-10 code
J02.9
ICD-10 code description
Sore throat (acute) NOS

Primary outcomes

1

Description
Sore throat
Timepoint
After remove of LMA and hours 2, 4 and 24 post operative
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Blood pressure,
Timepoint
Pre and post induction-end of operation and recovery
Method of measurement
Questionnaire

2

Description
pulse rate
Timepoint
Pre and post induction-end of operation and recovery
Method of measurement
Questionnaire

3

Description
sao2
Timepoint
Pre and post induction-end of operation and recovery
Method of measurement
Questionnaire

Intervention groups

1

Description
In intervention group, patients will be given 100 mg (2 mL) of intravenous hydrocortisone five minutes before anesthesia induction.
Category
Treatment - Drugs

2

Description
In control group, normal salin 2ml will be injected 5 min before anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Mahmoud eidy
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Tabriz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Reza Rashidi
Street address
Daneshghah Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mahmoud Eidy
Position
Associate Professor of Anesthesiology
Other areas of specialty/work
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Faculty of Medicine, Daneshghah Street
City
Tabriz
Postal code
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Email
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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty