

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

comparative assessment of applying beclomethasone spray and fluticasone spray on endotracheal tube cuff on postoperative sore throat in elective surgery patients

Protocol summary

Summary

The main objective of this study is comparing the effects of applying beclomethasone and fluticasone spray on endotracheal tube cuff on postoperative sore throat. This is a clinical trial on 90 patients who are selected for elective surgeries. Inclusion criteria: age 18 to 65 year; ASA classification of I and II; having no airway problem. Exclusion criteria: patients who may be traumatized during intubation; more than two times of trying for intubation; patients who need Succinylcholine injection. The patients will be divided into three following groups randomly: 1. Beclomethasone (200µg) spray is applied on the cuff of endotracheal tube (ETT) before intubation. 2. Fluticasone (200µg) spray is applied on the cuff of endotracheal tube (ETT) before intubation. 3. Normal saline is applied on the cuff of ETT before intubation. After induction of anesthesia, intubation is performed gently and this is done by a fixed person. After intubation cuff inflation is performed using Minimal Leak Technique. During operation we never manipulate ETT's cuff. In hours 1 and 24 after surgery, one who is blind to the study assesses the patients for sore throat. The severity of sore throat is determined according to VAS score and comparison is performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012812007N2**
Registration date: **2014-05-29, 1393/03/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-29, 1393/03/08

Registrant information

Name

Mohammad Reza Doroudian

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1246 2055

Email address

mdoroudian@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2014-04-01, 1393/01/12

Expected recruitment end date

2014-08-02, 1393/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative assessment of applying beclomethasone spray and fluticasone spray on endotracheal tube cuff on postoperative sore throat in elective surgery patients

Public title

assessment of applying beclomethasone spray and fluticasone spray on endotracheal tube cuff on postoperative sore throat

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 year; ASA classification of I and II; having no airway problem. Exclusion criteria: patients who may be traumatized during intubation; more than two times of trying for intubation; patients who need Succinylcholine injection; taking steroid therapy; head and neck or oral surgeries; laryngoscopy time more than 15 second; patients who take analgesics for 24 hours postoperatively.

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Informed consent is obtained from all subjects or their proxy and their rejection has no effect on normal treatment path. All intubations are performed by a same person who is blind to applied medication. The method of anesthesia in all is similar. Randomization is done by draw.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University Medical Sciences

Street address

Shafa Square

City

Kerman

Postal code

Approval date

2014-02-03, 1392/11/14

Ethics committee reference number

K/92/578

Health conditions studied

1

Description of health condition studied

Relation of applying beclomethasone spray and fluticasone spray on endotracheal tube cuff with postoperative sore throat in patient with surgery

ICD-10 code

J02.9

ICD-10 code description

Acute pharyngitis, unspecified

Primary outcomes

1

Description

sore throat

Timepoint

1 and 24 hours after surgery

Method of measurement

VAS score

Secondary outcomes

empty

Intervention groups

1

Description

Fluticasone (200µg) spray is applied on the cuff of endotracheal tube (ETT) before intubation (fluticasone 0.05 percent or 50 mcg fluticasone in each puff made by RAHA pharmaceutical Co.)

Category

Treatment - Drugs

2

Description

Beclomethasone (200µg) spray is applied on the cuff of endotracheal tube (ETT) before intubation (Beclomethasone Dipropionate, spray, dose 50 µg\puff, brand CLENIL, producer SINA DAROU LAB, quantity 200 puff)

Category

Treatment - Drugs

3

Description

Normal saline is applied on the cuff of ETT before intubation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bahonar Hospital
Full name of responsible person
Bahareh Mirzaee
Street address
Baghemelli Square
City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
City
Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Bahareh Mirzaei
Position
Assistant of anesthesiology
Other areas of specialty/work
Street address
Afzalipoor Hospital
City
Kerman
Postal code
Phone
+98 34 1322 2250
Fax
Email
bahar8700@gmail.com

Web page address Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mohammad Reza Doroudian
Position
Anesthesiologist
Other areas of specialty/work
Street address
Bahonar Hospital
City
Kerman
Postal code
Phone
+98 34 1223 5011
Fax
Email
javadkordi@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Bahareh Mirzaee
Position
Assistant of anesthesiology
Other areas of specialty/work
Street address
Baghemelli Square, Bahonar hospital
City
Kerman
Postal code
Phone
+98 34 1223 5011
Fax
Email
Web page address

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