

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison the effects of intravenous hydrocortisone and dexamethasone before extubation on Laryngospasm, cough and stridor after general anesthesia

#### Protocol summary

##### Summary

The aim of this study was to compare the effects of hydrocortisone and dexamethasone prior to extubation laryngospasm, coughing and stridor after general anesthesia. This is Clinical Trial, double-blind study with 108 patients, aged 15-55 years in hospital operating rooms of 15 Khordad in Bidokht and Hasheminejad in Mashhad. Patients class 1 and 2 ASA undergoing elective surgery (orthopedics, general surgery and urology) under anesthesia into two groups, Dexamethasone and hydrocortisone with intubation. Procedure to induce anesthesia in both fixed as premedication with midazolam 1-2mg, fentanyl 1-2 mcg / kg and induction of anesthesia with thiopental 5 mg / kg, neuromuscular. /5 mg / kg. The endotracheal tube cuff pressure to the extent that is not commensurate with the size and sex of patients Leakage will be selected. Group 1 and group 2 hydrocortisone 100 mg and dexamethasone 8 mg An intravenous dose 30 minutes before extubation receive back after swallowing reflex of the patient extubation laryngospasm, cough, stridor and the results of the questionnaire survey reflected.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015032520838N1**

Registration date: **2015-03-25, 1394/01/05**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-03-25, 1394/01/05

##### Registrant information

##### Name

Massoume Heidary karizaki

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51138679737

##### Email address

heidarykm1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Gonabad University of Medical Sciences

##### Expected recruitment start date

2015-01-30, 1393/11/10

##### Expected recruitment end date

2015-08-22, 1394/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effects of intravenous hydrocortisone and dexamethasone before extubation on Laryngospasm, cough and stridor after general anesthesia

##### Public title

Comparison the effects of intravenous hydrocortisone and dexamethasone before extubation on Laryngospasm, cough and stridor after general anesthesia

##### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients candidate for elective orthopedic surgery; general surgery and urology under general anesthesia with tracheal intubation ASA1,2 class in the age group 15- 55 years; Surgery less than 2 hours. Exclusion criteria: Larynx surgery;Respiratory disease; Difficult intubation; Require prolonged endotracheal intubation; Drug abuse.

### **Age**

From **15 years** old to **55 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **108**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Gonabad University of Medical Sciences

##### **Street address**

Next to the Asian road, Gonabad, Gonabad University of Medical Sciences

##### **City**

Gonabad

##### **Postal code**

#### **Approval date**

2015-01-07, 1393/10/17

#### **Ethics committee reference number**

GMU.REC.1393.95

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Stridor

#### **ICD-10 code**

j38.4

#### **ICD-10 code description**

Oedema of larynx

### **2**

#### **Description of health condition studied**

Laryngospasm - Cough

#### **ICD-10 code**

J95.8

#### **ICD-10 code description**

Post procedural respiratory disorders

## **Primary outcomes**

### **1**

#### **Description**

Laryngospasm

#### **Timepoint**

Afte extubation

#### **Method of measurement**

Clinical signs and score table laryngospasm

### **2**

#### **Description**

Cough

#### **Timepoint**

After extubation

#### **Method of measurement**

Clinical signs on the score sheet cough

### **3**

#### **Description**

Stridor

#### **Timepoint**

After extubation

#### **Method of measurement**

Clinical signs and stridor score table

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Group 1: Hydrocortisone 100 mg IV 30 minutes before to extubation

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Group 2: Dexamethasone 100 mg IV 30 minutes before to extubation

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

15 Khordad Hospital, Bidokht, Gonabad and Shahid Hasheminejad Hospital Mashhad

**Full name of responsible person**

Massoume Heidary Karizaki

**Street address**

Shahid Hasheminejad Hospital, Mashhad

**City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Dr. Ali Mohammadpour

**Street address**

Gonabad University of Medical Sciences

**City**

Gonabad

**Grant name**

-

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Gonabad 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**

Gonabad University of Medical Sciences

**Full name of responsible person**

Mahdi Basiri

**Position**

MSc. in Critical Care Nursing

**Other areas of specialty/work****Street address**

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+51 57 225813

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Arash Hamzei

**Position**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Massoume Heidary Karizaki

**Position**

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## 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*