

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Survey and Comparison of intravenous and intra-cuff Hydro cortisone on the severity of sore throat, cough and nausea after tracheal intubation during general anesthesia in distal limb fractures

Protocol summary

Summary

Objective: To determine the effect of intravenous and intra-cuff hydrocortisone on the severity of sore throat, cough and nausea after general anesthesia using endotracheal tube Design: A randomized triple-blind (patient, data collector, data analyzer) Study population: patients with distal limb fractures Setting and conduct: With block random allocation, patients will be included in three groups: A, B and C. After intubation, in group A, endotracheal tube cuff is filled with 100 mg hydrocortisone diluted with 5-10 ml distilled water and in group B, 100 mg diluted hydrocortisone is injected IV, and for group C, cuff is filled by 5-10 ml distilled water (routine). Main inclusion criteria: ASA class 1 and 2 anesthesia; lack of drug addiction; aged between 60-18 years; no sore throat or hoarseness prior to surgery Main exclusion criteria: Acute upper respiratory infections; the history of steroids and narcotics use in a week before surgery Sample size: 135 patients Interventions: 100 mg hydrocortisone diluted with 5-10 ml of distilled water inside the endotracheal tube cuff for group A, 100 mg diluted hydrocortisone IV for group B, and 5-10 ml of distilled water inside the cuff (routine) for group C.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603033064N3**
Registration date: **2016-07-20, 1395/04/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-20, 1395/04/30

Registrant information

Name

Hossein Bagheri

Name of organization / entity

Shahroud University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research (Research and Technology),
Shahroud University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey and Comparison of intravenous and intra-cuff Hydro cortisone on the severity of sore throat, cough and nausea after tracheal intubation during general anesthesia in distal limb fractures

Public title

Comparison of intravenous and intra-cuff Hydrocortisone on the severity of sore throat, cough and nausea after tracheal intubation during general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: ASA class 1 and 2 anesthesia; lack of drug addiction; aged between 60-18 years; no sore throat or hoarseness prior to surgery Main exclusion criteria: Acute upper respiratory infections; the history of steroids and narcotics use in a week before surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, patients will be placed in groups A and B and C. Then randomly will be assigned A letter to intravenous hydrocortisone group, B letter to intracuff hydrocortisone group and C letter to distilled water group and will be grouped into blocks of six by using software.

Secondary Ids

1

Registry name

...

Secondary trial Id

..

Registration date

2017-11-21, 1396/08/30

2

Registry name

...

Secondary trial Id

..

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahroud University of Medical

Sciences

Street address

Shahroud University of Medical Sciences, Hafte-Tir Square

City

Shahroud

Postal code

Approval date

2016-01-25, 1394/11/05

Ethics committee reference number

IR.SHMU.REC.1394.185

Health conditions studied

1

Description of health condition studied

Distal limb fractures

ICD-10 code

M84.9

ICD-10 code description

Disorder of continuity of bone, unspecified

Primary outcomes

1

Description

Cough

Timepoint

2, 6 and 24 hours after anesthesia

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Severity of sore throat

Timepoint

2, 6 and 24 hours after anesthesia

Method of measurement

Visual Analogue Scale (VAS)

3

Description

Nausea

Timepoint

2, 6 and 24 hours after anesthesia

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

...

Timepoint

...

Method of measurement

...

Intervention groups

1

Description

In the control group (group C), after intubation, endotracheal tube cuff will be filled with 5-10 ml of distilled water (routine)

Category

Treatment - Drugs

2

Description

In the intervention group (group B), 100 mg hydrocortisone diluted with 5-10 ml of distilled water, will be given intravenously.

Category

Treatment - Drugs

3

Description

In the intervention group (group A), after intubation, endotracheal tube cuff will be filled with 100 mg hydrocortisone diluted with 5-10 ml of distilled water

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein (AS) Hospital

Full name of responsible person

Dr. Javad Noorian

Street address

Imam Hossein (AS) Hospital, End of touhidi 28 meters, Imam street

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research - Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Hassan Emamian

Street address

Shahroud University of Medical Sciences, Hafte-Tir Square

City

Shahroud

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 - Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Bagheri

Position

Ph.D in Nursing

Other areas of specialty/work

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Postal code**Phone****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*