Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of hydrocortisone and placebo (distilled water) on hemodynamic changes in atracurium for intubation in patients with upper limb fractures (candidate for elective surgery)

Protocol summary

Study aim

Determination of the effect of hydrocortisone on hemodynamic changes including arterial blood pressure and heart rate resulting from the neuromuscular relaxant atracurium

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 48 patients. G * Power software was used for randomization.

Settings and conduct

The present study will be a double-blind randomized clinical trial (patient and outcome assessor) performed on individuals aged 15 to 60 years to determine the effects of hydrocortisone on hemodynamic changes induced by atracurium for intubation in patients under general anesthesia referred to 5 Azarshahr Medical Center. Gorgan will be done in 2022.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients for elective upper limb fracture surgery between the ages of 15-60 with ASA I or II, Exclusion criteria: neuromuscular disorders, receiving antibiotics including aminoglycosides 24 hours before surgery, liver disease And kidney, diabetes, heart failure, allergy to corticosteroids, obesity, taking H1 histamine blocker one day before surgery, lactating and pregnant mothers, psychotic disorders,hypothyroidism,Osteoporosis

Intervention groups

Intervention group: 100 mg Jaber hydrocortisone vial with the generic name: Hydrocortisone-Systemic (manufacturer of Jaber Bin Hayan Pharmacy [Iran]) once, 30 minutes before entering the operating room (in the ward) intravenously and bolus with 300 ml They receive normal saline under the supervision of a nurse who has no knowledge of the study groups. Control group: Individuals in the placebo group received the same amount of distilled water with 300 ml of normal saline under the supervision of a nurse who is unaware of the drug groups.

Main outcome variables

Hemodynamic changes Bronchospasm Number of breaths

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170108031818N2**
Registration date: **2022-04-20, 1401/01/31**
Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**
Update count: **0**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name
fatemeh mehravar
Name of organization / entity
Golestan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 912 893 7199
Email address
mehravar10261@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of hydrocortisone and placebo (distilled water) on hemodynamic changes in atracurium for intubation in patients with upper limb fractures (candidate for elective surgery)

Public title

Evaluation of the effects of hydrocortisone on hemodynamic changes in patients under general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients for elective surgery between the ages of 15-60 with ASA I or II

Exclusion criteria:

All patients for elective surgery between the ages of 15-60 with ASA I or II Metabolic and neuromuscular disorders People if they receive strong antibiotics effective on the effects of relaxants, including aminoglycosides 24 hours before surgery Significant liver and kidney disease Known allergies to narcotics and other drugs used during anesthesia if he took the H1 histamine blocker the day before surgery Obesity (if ideal body weight> 30)

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study were assigned to the intervention (B) and control (A) groups by block randomization. Using a dice that has 6 sides, the samples are assigned to their groups. A number is written on each side and each number is assigned to one of the blocks in the table, which has its own special mode. it shows. Group A (hydrocortisone) and B (placebo of distilled water). A complete list of randomized blocks was provided to the lead researcher by the study epidemiologist.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding in this study is double-blind. After obtaining the consent of the participants, they are blind to their study groups and the preparation and dilution of the drug, which are similar in appearance (size, shape, volume of the manufacturer) is done by the nurse in charge of the department. Minutes before entering the operating room (in the ward), people in the hydrocortisone group receive 100 mg of hydrocortisone intravenously and bolus with 300 ml of normal saline. The doctor in charge of the plan and the intervener will not know the type of drug group. Anesthesia induction will be performed by the project resident resident who has no role in the study outcome process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.GOUMS.REC.1400.318

Health conditions studied

1

Description of health condition studied

Patients for elective surgery for upper limb fractures

ICD-10 code

T10

ICD-10 code description

Fracture of upper limb, level unspecified

Primary outcomes

1

Description

hemodynamic changes

Timepoint

Hemodynamics will be recorded in the relevant list before the administration of hydrocortisone and 30 minutes after the administration of hydrocortisone or at the entrance to the operating room and 5 minutes after the peak effect of atracurium (before intubation) and after ecstasy.

Method of measurement

This monitoring will be performed under the supervision of an anesthesiologist based on patient monitoring instructions, including continuous monitoring of heart rate, arterial oxygen saturation and intermittent and non-invasive measurement of systolic and diastolic blood pressure and bronchospasm by Saadat's monitoring device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Individuals in the hydrocortisone group receive 100 mg of hydrocortisone intravenously and bolus with 300 ml of normal saline under the supervision of a nurse who is unaware of the drug groups.

Category

Treatment - Drugs

2

Description

Control group: Individuals in the placebo group receive the same amount of distilled water with 300 ml of normal saline under the supervision of a nurse who is unaware of the drug groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan 5 Azar Educational and Medical Center

Full name of responsible person

Kazem Kazemnejad Tabrizi

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City

gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3223 8363

Email

mehravar10261@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City

gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3223 8363

Email

honarvar@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Kazem Kazemnejad Tabrizi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City
Gorgan

Province
Golestan

Postal code
4934174515

Phone
+98 17 3223 8363

Email
mehravar10261@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Kazem Kazemnejad Tabrizi

Position
Associate Professor

Latest degree
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Other areas of specialty/work
Anesthesiology

Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City
Gorgan

Province
Golestan

Postal code
4934174515

Phone
+98 17 3223 8363

Fax

Email
mehravar10261@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
Kazem Kazemnejad Tabrizi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City
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Province
Golestan

Postal code
4934174515

Phone
+98 17 3223 8363

Email
mehravar10261@yahoo.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