

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Laryngeal Mask Airway impregnation with diltiazem gel on cardiovascular changes in patients with hypertension undergoing Fico surgery

Protocol summary

Study aim

The effect of Laryngeal Mask Airway impregnation with diltiazem gel on cardiovascular changes in patients with hypertension undergoing Fico surgery

Design

Clinical trial with control group and parallel groups, double blind, simple randomization

Settings and conduct

In patients in the intervention group, a laryngeal airway mask impregnated with diltiazem gel was used, and in patients in the control group, lubricant gel was used. The gels were named A and B by the research partner, and the researcher and patient were unaware of the type of gel.

Participants/Inclusion and exclusion criteria

Inclusion criteria: HTN patients undergoing Fico surgery with 16 to 55 years old, Exclusion criteria: Dysrhythmia, heart attack, pregnancy

Intervention groups

The intervention group includes patients with hypertension undergoing Fico surgery who receive Diltiazem gel intervention. The control group includes patients with hypertension undergoing Fico surgery who receive Lubricant gel intervention.

Main outcome variables

Hypertension, heart rate, dysrhythmia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047457N1**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **prospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

javad aminisaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3727 9104

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Laryngeal Mask Airway impregnation with diltiazem gel on cardiovascular changes in patients with hypertension undergoing Fico surgery

Public title

Investigation of the effect of diltiazem gel on cardiovascular changes in patients with hypertension undergoing Fico surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
HTN patients under Fico surgery Age range: 16 to 55 years old

Exclusion criteria:
Dysrhythmia Heart attack Pregnancy

Age
From **16 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization by random number table method

Blinding (investigator's opinion)
Double blinded

Blinding description
Researchers and participants have been kept blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences Research Ethics Committee

Street address

Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd., Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-05-11, 1399/02/22

Ethics committee reference number

IR.KUMS.REC.1399.131

Health conditions studied

1

Description of health condition studied

HTN patients

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

2

Description of health condition studied

Fico surgery

ICD-10 code

H59.029

ICD-10 code description

Cataract (lens) fragments in eye following cataract surgery

Primary outcomes

1

Description

hypertension

Timepoint

Before intubation, immediately after intubation and 5 min after intubation, during the operation every 15 minutes, the recovery, 15 and 30 minutes after entering the recovery

Method of measurement

Based on the monitoring device

Secondary outcomes

1

Description

Cardiac dysrhythmia

Timepoint

Before intubation, immediately after intubation and 5 min after intubation, during the operation every 15 minutes, the recovery, 15 and 30 minutes after entering the recovery

Method of measurement

Based on the monitoring device

2

Description

heart beat

Timepoint

Before intubation, immediately after intubation and 5 min after intubation, during the operation every 15 minutes, the recovery, 15 and 30 minutes after entering the recovery

Method of measurement

Based on the monitoring device

Intervention groups

1

Description

Control group: In the first intervention group, induction of anesthesia is performed with 2 mg / kg pro-pofol and atracurium 0.5 mg / kg, then the laryngeal airway mask is soaked in water-soluble neutral sterile lubricant gel.

Category

Treatment - Other

2

Description

Intervention group: In the second intervention group, induction of anesthesia is performed with 2 mg / kg of propofol and atracurium 0.5 mg / kg, then the laryngeal airway mask with 0.2% gel is dipped in water-soluble sterile diltiazem.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Kermanshah

Full name of responsible person

Javad Amini Saman

Street address

Imam Khomeini Hospital, Naqlieh St. , Kermanshah

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ihosp@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Javad Amini Saman

Position

Managing Director of Imam Khomeini Hospital in
Kermanshah

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital, Naqlieh St. , Kermanshah

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Javad Amini Saman

Position

Managing Director of Imam Khomeini Hospital in
Kermanshah

Latest degree
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Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Position
Researcher of Imam Khomeini Hospital Research Unit
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Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is shared
When the data will become available and for how long
Access period starting one year after the publication of results
To whom data/document is available
All researchers
Under which criteria data/document could be used
Use for future researchs
From where data/document is obtainable
Kermanshah University of Medical Sciences
What processes are involved for a request to access data/document
by Email
Comments