

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Investigation of the effect of impregnation of endotracheal tube cuff with diltiazem gel on cardiovascular changes in patients undergoing laparoscopic cholecystectomy Surgery.

Protocol summary

Study aim

Determination of the effect of impregnation of endotracheal tube cuff with diltiazem gel on cardiovascular changes in patients undergoing laparoscopic cholecystectomy Surgery

Design

Clinical trial with control group and parallel group, blinded , simple randomized

Settings and conduct

In the experimental group, the cuff of the endotracheal tube was impregnated with diltiazem gel, and in the control group , the lubricating gel was used for cuff. The gels were named by the research colleague of two types A and B, and the researcher and the patient were unaware of the gel type.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Having Gallstones Exclusion criteria: Dysrhythmia, Myocardial infarction,Hypertension history, Pregnancy

Intervention groups

In patients undergoing Cholecystectomy Surgery by Laparoscopic, the diltiazem gel is applied to the cuff of the endotracheal tube and its effect on cardiovascular disorders is investigated.

Main outcome variables

Blood pressure, heart rate, arrhythmia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190307042957N1**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **retrospective**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

Registration date

2019-04-29, 1398/02/09

Registrant information

Name

yarhosain safari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 3963

Email address

w.office@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of impregnation of endotracheal tube cuff with diltiazem gel on cardiovascular changes in patients undergoing laparoscopic cholecystectomy Surgery.

Public title

Investigation of the effect of diltiazem gel on cardiovascular changes in patients undergoing cholecystectomy Surgery.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Having gallstones

Exclusion criteria:

Dysrhythmia Myocardial infarction Hypertension history

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 randomized (Random numbers table)

Blinding (investigator's opinion)

Double blinded

Blinding description

Both researcher and subjects were blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of
Medical Sciences

Street address

Shahid Beheshti Blv., Kermanshah University of
Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6719995364

Approval date

2018-10-16, 1397/07/24

Ethics committee reference number

IR.KUMS.REC.1397.569

Health conditions studied

1

Description of health condition studied

Gallstones

ICD-10 code

K80.1

ICD-10 code description

Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description

Blood pressure

Timepoint

Before the intubation, immediately after the intubation and 5 minutes after the intubation, during the surgery every 15 minutes, at entering the recovery, 15 and 30 minutes after entering the recovery

Method of measurement

Based on monitoring device

2

Description

Cardiac Dysrhythmia

Timepoint

Before the intubation, immediately after the intubation and 5 minutes after the intubation, during the surgery every 15 minutes, at entering the recovery, 15 and 30 minutes after entering the recovery

Method of measurement

Based on recovery device

3

Description

Heart rate

Timepoint

Before the intubation, immediately after the intubation and 5 minutes after the intubation, during the surgery every 15 minutes, at entering the recovery, 15 and 30 minutes after entering the recovery

Method of measurement

Based on recovery device

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, induction of anesthesia with 2 mg / kg Propofol and Atracurium 0.5 mg / kg is performed, then, the trachea cuff is impregnated with Lubricant water soluble gel

Category

Treatment - Other

2**Description**

In the second intervention group, induction of anesthesia with 2 mg / kg Propofol and Atracurium 0.5 mg / kg is performed, then is impregnated with 0.2% water-soluble sterilizing Diltiazem gel (Polygell, manufactured by Paliz Iranian medicine).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Dr Yarhosain Safari

Street address

Parastar ave. Emam Reza Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

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Shahid Beheshti Ave., Department of Kermanshah Medical Sciences

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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

50

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

Parastoo Abaspour

Position

clerk

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Javad Amini Saman

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Start the access period one year after the print results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Use for future research

From where data/document is obtainable

Kermanshah University of Medical Sciences

What processes are involved for a request to access data/document

via email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Parastoo Abaspour

Position

clerk

Latest degree

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Other areas of specialty/work

Psychology

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