

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effect of Ketofol (combination of Ketamin and Propofol) with Propofol during anesthesia induction on hemodynamic changes in patients undergo laparotomy

Protocol summary

Summary

Objectives: Blood pressure and heart rate changes during anesthesia induction with intravenous anesthetic agents are common complications in laparotomy. The aim of this study is to prevent these complications with the usage of a combined drug (Propofol and Ketamin).

Design: In this clinical trial 90 patients who are candidate for laparotomy under general anesthesia will be randomly divided into two groups; the control group and the trial group (each group has 45 members). Age, sex and other patients' information such as type of the surgeries and past medical histories will be documented.

Setting and conduct: The patients in the trial group will receive Ketofol (combination of Ketamin and Propofol) for general anesthesia induction and the patients in the control group will receive just Propofol for anesthesia induction. The intubation method is the same in the patients of both groups. Major inclusion and exclusion criteria: Patients who are candidate for laparotomy under general anesthesia with ASA class 1 in NPO condition, with neither urgent circumstances nor underline diseases. Intervention: Receiving Ketofol or Propofol intravenously. Main outcome measures (variables): Mean heart rate, systolic blood pressure and diastolic blood pressure will be assessed in 4 times before and after anesthesia induction and be compared with each other in the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021819037N6**
Registration date: **2015-03-05, 1393/12/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-05, 1393/12/14

Registrant information

Name

Mahdieh Yousef-Zanjani

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

Email address

yusefi.mahdieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-09-16, 1393/06/25

Expected recruitment end date

2015-03-16, 1393/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Ketofol (combination of Ketamin and Propofol) with Propofol during anesthesia induction on hemodynamic changes in patients undergo laparotomy

Public title

Comparison of the effect of Ketofol with Propofol on

patients' vital sign changes during laparotomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 20 to 60 years of age who are candidate for laparotomy (including appendectomy, gastrectomy, cholecystectomy and other kinds of laparotomy) under general anesthesia and are in ASA class 1 (The American Society of Anesthesiologists Physical Status classification system): Normal healthy patients with no organic, physiologic, or psychiatric disturbance. Exclusion criteria: Patients who use cardiac or anti-hypertensive or analgesic or sedative agents, patients who are not NPO (nil per os), diabetic or pregnant patients.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study the candidate patients for laparotomy will be randomly divided into one of the groups (trial or control) by usage of colored carts.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bamonar Boulevard

City

Qazvin

Postal code

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

28.20.8950

Health conditions studied

1

Description of health condition studied

Heart rate instability due to anesthesia

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Blood pressure instability due to anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean heart rate

Timepoint

In 4 times: before induction, 3, 5 and 10 minutes after induction

Method of measurement

The monitor device

2

Description

Mean systolic pressure

Timepoint

In 4 times: before induction, 3, 5 and 10 minutes after induction

Method of measurement

The monitor device

3

Description

Mean diastolic pressure

Timepoint

In 4 times: before induction, 3, 5 and 10 minutes after induction

Method of measurement

The monitor device

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (trial): Receiving handmade drug, Ketofol: 10 ml Propofol solution (10 mg/ml, from Fresenius Kabi drug manufacturing company, Germany) with 10 ml Ketamin solution (50 mg/ml, from Rotxmedica drug manufacturing company, Germany). One dose of

the combined solution was admitted for the patients intravenously for anesthesia induction (1.5 mg/kg).

Category

Other

2

Description

Second intervention group (control): Receiving Propofol solution (10 mg/ml, from Fresenius Kabi drug manufacturing company, Germany). One dose of this drug was admitted for the patients intravenously for anesthesia induction (1.5 mg/kg).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat General Hospital

Full name of responsible person

Dr. Hamid Kayalha

Street address

Taavon Square

City

Qazvin

2

Recruitment center

Name of recruitment center

Shahid Rajayi Hospital

Full name of responsible person

Dr. Hamid Kayalha

Street address

Taavon Square

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr. Mohammad Kolahdouzha

Street address

Velayat Hospital, Taavon Square

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Investigator

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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hamid Kayalha

Position

Professor, Anesthesiologist

Other areas of specialty/work

Street address

Shahid Bahonar Boulevard

City

Qazvin

Postal code

Phone

+98 28 3333 6004

Fax

Email

mohammad.kolahdouzha2050@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Velayat General Hospital

Full name of responsible person

Dr. Mohammad Kolahdouzha

Position

Anesthesiology Resident

Other areas of specialty/work

Street address

Taavon Square

City

Qazvin

Postal code

Phone

+98 28 3379 0620

Fax

Email

mohammad.kolahdouzha2050@gmail.com

Web page address

Person responsible for updating data

Contact

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