

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of time pause between the administration of midazolam and ketamine on post- anesthetic delirium of ketamine in minor gynecologic surgeries

Protocol summary

2016-02-26, 1394/12/07

Summary

The aim of this study was to evaluate the latency interval effect of midazolam and ketamine's post-anesthetic delirium in minor gynecologic surgeries. Informed consent will be obtained after patients enter operating room. In this randomized double blind clinical trial 100 women undergoing minor gynecological surgeries are assigned to 4 groups according to the time intervals of 0, 2.5, 5, 7.5 minutes between midazolam (0.05 mg/kg) and ketamine (1.5 mg/kg) doses administrated. Inclusion criterion: Women aged 16-50 with minor gynecologic surgeries which last less than 20 minutes, elective surgery, sent to recovery room after surgery, class ASA I & II. Exclusion criterion: History of sensitivity to midazolam or ketamine, history of psychiatric and neurological illnesses, history of heart disease and/or kidney failure under treatment, addiction to drugs or psychotropic substances, body mass index of over 30 or under 18. The patients' degree of tranquility, speech, and delirium which are considered as components of delirium are evaluated after complete awakening and obeying commands till discharge from the recovery room. The researcher who will be recording the intensity of delirium in recovery room is blinded to the time intervals.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010518091N7**

Registration date: **2016-02-26, 1394/12/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Fekrat Fereydoon

Name of organization / entity

Hormozgan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Governmental resources of Shariati Hospital of Bandar Abbas, Hormozgan University of Medical Sciences

Expected recruitment start date

2016-01-10, 1394/10/20

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of time pause between the administration of midazolam and ketamine on post- anesthetic delirium of ketamine in minor gynecologic surgeries

Public title

Does applying different time intervals between administering midazolam and ketamine affect the the delirium effect of ketamine in minor gynecologic

surgeries after the patient has awakened from anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: women aged between 16-56 years old with minor gynecologic surgeries which last less than 20 minutes; elective surgery; sent to recovery after surgery; class ASA I & II. Exclusion criterion: history of sensitivity to midazolam or ketamine; history of psychiatric and neurological illnesses; history of heart disease and/or kidney failure under treatment; addiction to drugs or psychotropic substances; body mass index of over 30 or under 18.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy for Research, and Medical Ethics Committee of Hormozgan University of Medical Sciences

Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital,

City

Bandar Abbas

Postal code

7919915519

Approval date

2014-11-11, 1393/08/20

Ethics committee reference number

3-HEC-93-8-20

Health conditions studied

1

Description of health condition studied

Delirium after ketamine administration in minor gynecological operations

ICD-10 code

F05.8

ICD-10 code description

Postoperative delirium

Primary outcomes

1

Description

Rest Score

Timepoint

After being able to obey to commands in recovery room

Method of measurement

screening scale (1 = very calm, 2 = calm, 3 = restless, 4 = very restless, 5 = extremely restless)

2

Description

Talk Score

Timepoint

After being able to obey to commands in recovery room

Method of measurement

(1 = very quiet, 2 = quiet, 3 = talked a little, 4 = talked a lot, 5 = called or cried out)

3

Description

Delirium Score

Timepoint

After being able to obey to commands in recovery room

Method of measurement

(1 = definitely not, 2 = no, 3 = perhaps, 4 = yes, 5 = definitely yes)

Secondary outcomes

empty

Intervention groups

1

Description

First group (zero minute): administering intravenous midazolam 0.05 mg/kg and immediately after this administering intravenous ketamine 1.5 mg/kg

Category

Treatment - Drugs

2

Description

Second group (two and half minutes): administering intravenous midazolam 0.05 mg/kg and after 2.5 minutes administering intravenous ketamine 1.5 mg/kg

Category

Treatment - Drugs

3**Description**

Third group (five minutes): administering intravenous midazolam 0.05 mg/kg and after 5 minutes administering intravenous ketamine 1.5 mg/kg

Category

Treatment - Drugs

4**Description**

Forth group (seven and half minutes): administering intravenous midazolam 0.05 mg/kg and after 7.5 minutes administering intravenous ketamine 1.5 mg/kg

Category

Treatment - Drugs

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

Shariati Hospital of Bandar Abbas

Full name of responsible person

Majid Vatankhah

Street address

Shahid Naseri blvd., Kansolgari, Shariati Hospital

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Bandar Abbas

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

Hormozgan University of Medical Sciences

Full name of responsible person

Abdulazim Nejatizadeh

Street address

Deputy of Research Center, Shahid Mohammadi Hospital, Joomhoori Islami blvd.

City

Bandar Abbas

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hormozgan 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**

Hormozgan University of Medical Sciences

Full name of responsible person

Majid Vatankhah

Position

Anesthesiology and Intensive care sub-specialist

Other areas of specialty/work**Street address**

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

Anesthesiology, Critical Care and Pain Management Research Center, Hormozgan University of Medical S

Full name of responsible person

Hashem Jarineshin

Position

Assistant Professor of Anesthesiology and Intensive care, Fellowship of Cardiac Surgery Anesthesia

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Full name of responsible person

Fereydoon Fekrat

Position

Specialist in Anesthesiology and Intensive care

Other areas of specialty/work

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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