Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

2016-02-26, 1394/12/07

Registrant information

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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
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hormozgan University of Medical Sciences
Full name of responsible person
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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
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Person responsible for scientific inquiries

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Full name of responsible person
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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