

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Ketamine versus Tramadol as an adjuvant to Bupivacaine in Spinal anesthesia

Protocol summary

Study aim

The aim of this study is to compare the effects of ketamine and tramadol on the onset, and duration of sensory and motor block, hemodynamic effects, and their adverse effects when used intrathecal as adjuvants to hyperbaric 0.5% bupivacaine for spinal anesthesia.

Design

Randomized controlled trail

Settings and conduct

Sensory block observed by pinprick, while the motor block observed by modified bromage score (0:no loss, 1: unable to flex the hip, 2: unable to flex the knee, 3: unable to flex the ankle) Four-point scale used to assess the sedation every 10 min (1: awake,2: drowsy and response to verbal command,3: response to physical stimulation, 4: unresponsive to verbal command and physical stimulation).

Participants/Inclusion and exclusion criteria

Inclusion: ages of 16- 45 years ASA class 1 and 2 selective unilateral open ovarian cystectomy. exclusion: spine deformity bleeding tendency mental disturbance neurological diseases history of scorpion bite ASA 3 or more

Intervention groups

Group 1 is the control group receiving 2 ml of hyperbaric Marcaine 0.5% mixed with 1ml of normal saline. Group 2 receiving 2 ml of hyperbaric Marcaine 0.5% mixed with ketamine (25 mg), and Group 3 receiving 2 ml of hyperbaric Marcaine 0.5% mixed with tramadol (25 mg). In all three groups the volume completed to 3 ml with normal saline.

Main outcome variables

onset of sensory block (min) duration of sensory block (min) onset of motor block (min) duration of motor block (min) Duration of spinal analgesia (min) Nausea Vomiting Headache Pruritus Shivering Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230813059138N1**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **prospective**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

Registration date

2023-08-23, 1402/06/01

Registrant information

Name

Ammar Al-Nussairi

Name of organization / entity

Sousse university, Ibn Aljazzar college of medicine

Country

Iraq

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+964 770 578 7925

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-26, 1402/06/04

Expected recruitment end date

2024-02-15, 1402/11/26

Actual recruitment start date

2023-08-26, 1402/06/04

Actual recruitment end date

2024-03-15, 1402/12/25

Trial completion date

2024-05-01, 1403/02/12

Scientific title

Ketamine versus Tramadol as an adjuvant to Bupivacaine in Spinal anesthesia

Public title

Spinal anesthesia additives

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female Age between (16-45 years) ASA class 1 or 2 elective open unilateral ovarian cystectomy

Exclusion criteria:

spine deformity bleeding tendency neurological diseases history of scorpion bite patient disapproval

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple, individual randomization will be occur by a person who is not considered as a participant in this clinical trial by using special sample randomization software by Microsoft Excel, randomization will occur on a 1:1:1 ratio of bupivacaine to bupivacaine plus ketamine to bupivacaine plus tramadol. the person will give a random sequence to the solutions of study , and this preparation will send to a second person who does not know the exact solution. All bupivacaine , bupivacaine plus ketamine, and bupivacaine plus tramadol solutions are unknown and will be keep in a box. The participants and the researcher will not be able to distinguish the type of solution that will administer to the patient. Directly after administering the solution the observer will records all required variables data, Although he also do not know the exact administered solution. At the full end of each single patient data collection, the person who previously had gave a random sequence will open the codes to records the real administered solution on patient's special form of data.

Blinding (investigator's opinion)

Double blinded

Blinding description

explain the plan for colleagues previously. when the patient came he took an ID which is previously allocated randomly in groups by using Microsoft excel. the study solution was prepared by an anesthetist who did not involved in data collection. the observation and collecting of data done by other anesthetist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of research's in Diyala health directorate- Iraqi ministry of health

Street address

7 Nissan Ave., main Ave., Baquba city., Diyala governorate., Republic of Iraq

City

Baquba

Postal code

32000

Approval date

2022-07-04, 1401/04/13

Ethics committee reference number

The form number 2021/3- Documented number 75

Health conditions studied

1

Description of health condition studied

additives in spinal anesthesia

ICD-10 code

N83.20

ICD-10 code description

Ovarian cyst, unilateral. unspecified

Primary outcomes

1

Description

Primary outcome were the onset and duration of both sensory and motor block, and the duration of spinal analgesia

Timepoint

3 days after intervention

Method of measurement

sensory block by pinprick, while the motor block observed by modified bromage score

Secondary outcomes

1

Description

The secondary outcome were, nausea, vomiting, sedation, shivering, heart rate, mean arterial pressure

Timepoint

directly after intervention till 3 days after intervention

Method of measurement

inspection (visually) observation

Intervention groups**1****Description**

Control group: receiving 2ml of hyperbaric bupivacaine 0.5%. After Fasting period of 6 hours, patient received intravenous preload of 10 ml/kg of either N/S or ringer solution. No premedication where given because the effects of these drugs may intervene with some of result that observed such as sedation or nausea and/or vomiting and other variables. patient in sitting position acupuncture given with midline technique under aseptic environment at the level of L3/L4, orifice oriented cephalad needle G25 was used. The study solution injected at the same adequate speed for all the patient then convert the patient to supine position. The volume of study's liquid increased to 3 ml by normal saline for all control and intervention groups.

Category

Treatment - Drugs

2**Description**

Intervention group 1: receiving 2ml of hyperbaric bupivacaine 0.5% plus ketamine (25 mg). After Fasting period of 6 hours, patient received intravenous preload of 10 ml/kg of either N/S or ringer solution. No premedication where given because the effects of these drugs may intervene with some of result that observed such as sedation or nausea and/or vomiting and other variables. patient in sitting position acupuncture given with midline technique under aseptic environment at the level of L3/L4, orifice oriented cephalad needle G25 was used. The study solution injected at the same adequate speed for all the patient then convert the patient to supine position. The volume of study's liquid increased to 3 ml by normal saline for all control and intervention groups.

Category

Treatment - Drugs

3**Description**

Intervention group 2: receiving 2ml of hyperbaric bupivacaine 0.5% plus tramadol (25 m). After Fasting period of 6 hours, patient received intravenous preload of 10 ml/kg of either N/S or ringer solution. No premedication where given because the effects of these drugs may intervene with some of result that observed such as sedation or nausea and/or vomiting and other variables. patient in sitting position acupuncture given with midline technique under aseptic environment at the level of L3/L4, orifice oriented cephalad needle G25 was used. The study solution injected at the same adequate

speed for all the patient then convert the patient to supine position. The volume of study's liquid increased to 3 ml by normal saline for all control and intervention groups.

Category

Treatment - Drugs

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

Balad Ruz general hospital

Full name of responsible person

Abbas Al Bakri

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Zeraa Avenue., Main Avenue., Alban square., Balad Ruz., Diyala., Iraq

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

University of Sousse, Faculty of Medicine Ibn Al Jazzar

Full name of responsible person

Dr. Mohamed Kahloul

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famso@famso.rnu.tn

Web page address

<https://uso.rnu.tn/>

Grant name

Null

Grant code / Reference number

000

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

No

Title of funding source

University of Sousse, Faculty of Medicine Ibn Al Jazzar

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

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

University of Sousse, Ibn Al Jazzar College of medicine

Full name of responsible person

Dr. Mohamad Kahloul

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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

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Position

Ph.D. student

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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

Undecided - It is not yet known if there will be 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 collected deidentified IPD

When the data will become available and for how long

8 months after publication

To whom data/document is available

Researcher, and academic institute.

Under which criteria data/document could be used

the data will be available for supporting academic study to improve the study that needs these data like meta analysis study.

From where data/document is obtainable

Email: ammar.hoom88@gmail. cellphone: 009647705787925

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

Introducing them selves, and give logical reason behind needing this data will be enough to supply them.

Comments