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
Grouo1 is the control group receiving 2 ml of hyperbaric Marcaine 0.5% mixed with 1ml of normal saline. Group 2receiving 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) Nausia 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
Phone
+964 770 578 7925
Email address
ammar.hoom88@gmail.com

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., Repoblic 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
Street address
Zeraa Avenue., Main Avenue., Alban square., Balad Ruz., Diyala., Iraq
City
Blad Ruz city
Postal code
3200
Phone
+964 770 578 7925
Email
baladruzgeneralhospital@yahoo.com

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
Street address
Avenue Mohamad Karoui 4002 Sousse B.P:126
City
Sousse
Postal code
4023
Phone
+216 73 222 600
Fax
+216 73 224 899
Email
famso@famso.rnu.tn
Web page address
https://uso.rnu.tn/
Grant name
Nill
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
Anesthesiology
Street address
Avenue Mohamad Karoui 4002 Sousse B.P:126
City
Sousse
Province
Sousse
Postal code
4000
Phone
+216 73 222 600
Email
famso@famso.rnu.tn

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Sousse, Ibn al Jazzar college of medicine
Full name of responsible person
DRr Mohamad Kahloul
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Avenue Mohamad Karoui 4002
City
Sousse
Province
Sousse
Postal code
4000
Phone
+216 73 222 600
Email
famso@famso.rnu.tn

Person responsible for updating data

Contact
Name of organization / entity
University of Sousse, Faculty of Medicine Ibn Al Jazzar, Sousse
Full name of responsible person
Ammar Al-Nussairi
Position
Ph.D. student
Latest degree
Master
Other areas of specialty/work
Anesthesiology
Street address
Zeraa Ave., Main Ave., Albaan square., Balad Ruz city
City
Balad- Ruz city
Province
Diyala
Postal code
3200
Phone
+964 770 578 7925
Email
ammar.hoom88@gmail.com

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