Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determination of subcutaneous infiltration of ketamine for sedation in patients undergoing TUL surgery under spinal anesthesia in Ahwaz Imam Khomeini hospital in 1397-1398

Protocol summary

Study aim

Determination of the effect of subcutaneous ketamine infiltration for sedation in candidate patients with TUL surgery.

Design

60 patients will be examined for TUL elective surgery in Imam Khomeini Hospital in Ahvaz, which had the conditions to enter the study. Patients will be randomly divided into control and test groups. Patients will receive subcutaneous ketamine intervention. Patients in the control group received the same amount of placebo subcutaneously.

Settings and conduct

After entering the operating room, standard monitor including noninvasive blood pressure (NIBP), electrocardiogram (ECG) and pulse oximetry (SPO2) will be attached to the patient and the base rate will be recorded. The intravenous catheter will be fixed with cannula number 18. Patients will take 10-15 ml / kg of lactate Ringer. Patients will undergo spinal anesthesia (12mg for height less than 160cm, 12.5mg for height 175-160cm and 13mg for height above 175cm). Bupivacaine 0.5% with Needle No. 25 will be injected in l2-l3 space by Mid-line method. Then spinal cord Cerebrospinal fluid aspiration and 0.5% vacuum injection will be performed in both groups.

Participants/Inclusion and exclusion criteria

Criteria for entering: Patients aged 18-70 years, Candidate of TUL surgery, Class ASAI-II. Criteria for not entering: History of hypertension, hyperthyroidism, psychiatric disorders, ketamine allergy, renal or hepatic insufficiency, convulsions or intracranial hypertension ,drug abuse in six months, spinal anesthesia contraception.

Intervention groups

Patients in the intervention group will receive 0.5 mg / kg of subcutaneous ketamine and will receive o2 facial mask therapy with flow = 5lit / min. Patients in the control group will receive subcutaneous placebo and will receive o2 facial mask therapy with flow = 5lit / min.

Main outcome variables

Respiratory rate, heart rate, blood pressure, pain rate, chills rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191227045906N1**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-14, 1399/02/25**
Update count: **0**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

Soheila daneshmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 0755

Email address

daneshmand.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-08, 1398/11/19

Expected recruitment end date

2020-07-09, 1399/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of subcutaneous infiltration of ketamine for sedation in patients undergoing TUL surgery under spinal anesthesia in Ahwaz Imam Khomeini hospital in 1397-1398

Public title

Determination of subcutaneous infiltration of ketamine for sedation in patients undergoing TUL surgery under spinal anesthesia in Ahwaz Imam Khomeini hospital in 1397-1398

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Spinal anesthesia contraindication TUL surgery candidate ASAI-II class

Exclusion criteria:

History of hypertension Hyperthyroidism Psychiatric disorders Allergy to ketamine Kidney or liver failure Intracranial seizures or hypertension Drug or drug abuse within six months Spinal anesthesia contraindication

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Given that in the present study we have two study groups (intervention group = A and control group = B). Then, with the help of the table of random numbers, we assign the numbers 0-4 of the table to block 1 (AB) and the numbers 5-9 of the table to block 2 (BA). We provide a random list of 30 people for each group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Department of Anesthesiology, School of Medicine, Ahvaz Jundishapur University of Medical Sciences,

Street address

Golestan area- Ahvaz Jundishapur University of Medical Sciences, Ahwaz

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2020-02-08, 1398/11/19

Ethics committee reference number

IR.AJUMS.REC.1398.852

Health conditions studied

1

Description of health condition studied

Urological services with urine virtual stone

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

RR

Timepoint

Continuously and every 15 minutes

Method of measurement

It will be continuously measured during the operation and will be recorded and specified every 15 minutes by the capnogram.

2

Description

HR

Timepoint

Continuously and every 15 minutes

Method of measurement

It will be continuously measured during the operation and will be recorded every 15 minutes by ECG

3

Description

BP

Timepoint

Continuously and every 15 minutes

Method of measurement
It will be continuously measured during the operation and will be recorded every 15 minutes by NIBP

4

Description
pain
Timepoint
Every 30 min in operation room and one hour and two hours after surgery in recovery
Method of measurement
The amount of pain is measured according to the VAS

5

Description
Chill rate
Timepoint
At zero times, 30 minutes, one hour and two hours after the end of surgery and in recovery
Method of measurement
It will be measured based on observation and questioning of the patient and based on crossley division.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive 0.5 mg / kg of subcutaneous ketamine and will receive o2 facial mask therapy with flow = 5lit / min.
Category
Treatment - Surgery

2

Description
Control group: Patients in the control group will received the same amount of placebo subcutaneously. They will then undergo o2 therapy with a face mask with Flow = 5lit / min.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Ahvaz
Full name of responsible person
Soheyla Daneshmand
Street address
24m Street - Not reached the Black Bridge
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3292 3985
Fax
+98 61 3222 5763
Email
himam@ajums.ac.ir
Web page address
https://himam.ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Boulevard of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3336 5975
Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Kaveh Behaeen
Position
Faculty members from the University of Medical

Sciences
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Position
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Latest degree
Specialist
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Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Soheyla Daneshand
Position
Anesthesiology Assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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39345-61355.
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009833337077
Fax
Email
dr.daneshmand98@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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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 potential data can be shared after unidentifiable people
When the data will become available and for how long
Start of access will 12 months after publication of results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Academic Scientific Research
From where data/document is obtainable
Ahvaz Jundishapur University of Medical Sciences
What processes are involved for a request to access data/document
Acquiring the permissions from Ethics Committee and University Research Committee
Comments