Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of Intrathecal injection of Pethidine with Bupivacaine on pain control in Appendectomy Surgery under regional Anesthesia

Protocol summary

Study aim
Investigating the effect of Intrathecal injection of Pethidine with Bupivacaine on pain control in appendectomy surgery under Regional Anesthesia.

Design
According to G POWER application our sample size is about 74. We use block randomization and we divide participant into two groups, A for target group and B for control group. This is a double blinded research.

Settings and conduct
After hemodynamic assesment we keep the patients in sitting position and do spinal anesthesia with quinke 25 needle. In control group we use 12.5 mg bupivacaine with 0.5 cc normal saline and in target group we use 12.5mg bupivacaine with 0.5 cc (25mg) pethidine. The anesthesiology resident do not know about the drug that we use and inject the drug in L2-L3 intrathecal space and after anesthesia reach T6-T8 sensory level we start the surgery.

Participants/Inclusion and exclusion criteria
Patient between 18 to 60 years of age with acute appendicitis and ASA 1 or 2.

Intervention groups
In this research we inject bupivacaine with pethidine in target group and bupivacaine with normal saline in control group and we evaluate the effect of pethidine on pain in patient under surgery.

Main outcome variables
In this reaserch we believe that adding pethidine to local anesthetic can prevent visceral pain in appendectomy surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241022063464N1**
Registration date: **2024-12-24, 1403/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-24, 1403/10/04**
Update count: **0**

Registration date
2024-12-24, 1403/10/04

Registrant information

Name
SOROUSH SHEYDAIE

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3890 5592

Email address
s.sh19441@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-20, 1403/09/30

Expected recruitment end date
2025-04-20, 1404/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Intrathecal injection of Pethidine with Bupivacaine on pain control in Appendectomy Surgery under regional Anesthesia

Public title
The effect of Intrathecal injection of Pethidine with Bupivacaine on pain control in Appendectomy Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-60 years old Had a informed consent Acute appendicitis ASA 1 OR 2
Exclusion criteria:
Allergy to bupivacaine Allergy to meperidine BMI>30 Difficulty with regional anesthesia(no premission-scoliosis-site infection-neuropathy) Opium addiction
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind clinical trial.after infromed patient about procedure,anesthesiologist professor prepare the syringes and resident will do the spinal anesthesia and record the data.patient and resident do not know about the drug that injected in intrathecal space.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Golestan university of medical science
Street address
5Azar hospital.,5Azar blvd
City
Gorgan
Province
Golestan
Postal code
1111111111
Approval date
2024-10-19, 1403/07/28
Ethics committee reference number
IR.GOUMS.REC.1403.241

Health conditions studied

1

Description of health condition studied
Appendicitis
ICD-10 code
K35.2
ICD-10 code description
Acute appendicitis with generalized peritonitis

Primary outcomes

1

Description
Pain
Timepoint
Every 5 minute
Method of measurement
VAS(visual analogue scale)

Secondary outcomes

1

Description
Blood pressure
Timepoint
Every 5 min
Method of measurement
Non invase blood pressure

Intervention groups

1

Description
Intervention group: group that we inject 12.5mg bupivacaine plus 25mg pethidine in L2-L3 space
Category
Treatment - Drugs

2

Description
Control group: We inject 12.5 mg bupivacaine plus 0.5 cc strile normal saline in l2-l3 on control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5Azar hospital
Full name of responsible person
Babak mojaver aghili
Street address
5Azar hospital.,5Azar blvd
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4356437895
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Babak mojaver aghili
Position
Associated professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
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 date will released anonymously

When the data will become available and for how long
One year after publishing

To whom data/document is available
Anesthesiologists

Under which criteria data/document could be used
.

From where data/document is obtainable
soroush sheydaie email: s.sh19441@gmail.com

What processes are involved for a request to access data/document
Send email to me please

Comments