Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of ultrasound guided erector spinal plane block with intra-venous fentanyl in the management of refractory renal colic pain

Protocol summary

Study aim

Comparison of ultrasound guided erector spinae plane block with intra-venous fentanyl in the management of refractory renal colic pain

Design

clinical trial with two factorial groups was performed randomly on 40 patients.

Settings and conduct

This study was performed in Bahonar Hospital of Kerman University of Medical Sciences. In one group with refractory renal colic, the spina erector block method was used. In the second group, fentanyl with a starting dose of 1 µg / kg was injected slowly intravenously and under monitoring.

Participants/Inclusion and exclusion criteria

The study population was patients 20-65 years who had renal colic.

Intervention groups

In the group 1, which includes the spina erector block, using the 7.5 MHz (surface) probe of the ultrasound device, which is placed in the paravertebral region (between 5 to 10 cm from the midline) and at the perimeter of the T5 vertebra, the appendix Identification of the vertebrae and fascia of the erected spinach to which it is attached, and needle number 20 under sterile conditions and after permeation under ultrasound-guided approach to the nerve sheath and 20 cc of 1% lidocaine (in patients with the ideal weight below 90 and above 65 kg is calculated based on 4.5 mg / kg of 1% lidocaine solution) at the injection site and diffusion of anesthetic fluid was observed under the fascia of the spina erector. In the group 2, fentanyl with a starting dose of 1 µg / kg was injected slowly intravenously and under monitoring.

Main outcome variables

Complications that can be attributed to any method include headache, nausea, vomiting, dyspnea, arrhythmia and local complications (artery and vein perforation, nerve damage, hematoma) and systemic complications of lidocaine injection and patient satisfaction score in each group of 1 (lowest satisfaction) To 4 (maximum satisfaction).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220113053709N1**
Registration date: **2022-01-24, 1400/11/04**
Registration timing: **retrospective**

Last update: **2022-01-24, 1400/11/04**
Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

Javad Darijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

j.darijani@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

2021-12-22, 1400/10/01

Actual recruitment end date

2022-01-20, 1400/10/30

Trial completion date
2022-01-20, 1400/10/30

Scientific title
Comparison of ultrasound guided erector spinal plane block with intra-venous fentanyl in the management of refractory renal colic pain

Public title
Comparison of ultrasound guided erector spinal plane block with intra-venous fentanyl in the management of refractory renal colic pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The study population was patients 20-65 years who had renal colic.

Exclusion criteria:
Patients who had distracting injury Patients who had not full consciousness or cognitive activity Patients who had a history of allergies to Lidocaine and fentanyl Patients who had diseases that interfere with the procedure or pain rating (such as bleeding defects or peripheral neuropathy) Patients who did not agree to participate in the study or local block

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was performed by simple randomization using Random software allocation and demographic similarity between the two groups (including age and sex, etc.) was checked. The sample subjects were selected by easy sampling method and were divided into two groups based on the numbers generated by the software. After being randomly placed between the two groups, the individuals underwent one of the two procedures after confirming the informed consent form.

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
Ethics committee of Afzalipour educational and Medical Center- Kerman University of Medical Sciences

Street address
Somayeh Crossroads (Tahmasb Abad)

City
Kerman

Province
Kerman

Postal code
7619813159

Approval date
2021-12-20, 1400/09/29

Ethics committee reference number
IR.KMU.AH.REC.1400.226

Health conditions studied

1

Description of health condition studied
Renal colic

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
pain score

Timepoint
pain score in the start, 30 minute and 60 minute

Method of measurement
Iowa questionnaire

Secondary outcomes

1

Description
complication

Timepoint
start, 30 minute, 60 minute

Method of measurement
Checklist

Intervention groups

1

Description
Intervention group: n the first group, which includes the

spina erector block, using the 7.5 MHz (surface) probe of the ultrasound device, which is placed in the paravertebral region (between 5 to 10 cm from the midline) and at the perimeter of the T5 vertebra, the appendix Identification of the vertebrae and fascia of the erected spinach to which it is attached, and needle number 20 under sterile conditions and after permeation under ultrasound-guided approach to the nerve sheath and 20 cc of 1% lidocaine (in patients with the ideal weight below 90 and above 65 kg is calculated based on 4.5 mg / kg of 1% lidocaine solution) at the injection site and diffusion of anesthetic fluid was observed under the fascia of the spina erector.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, fentanyl with a starting dose of 1 µg / kg was injected slowly intravenously and under monitoring.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bahonar hospital

Full name of responsible person
Mehdi Torabi

Street address
Qharani street

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 3223 5011

Email
j.darijani@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr Reza Malek Pourafshar

Street address
Somayeh Crossroads (Tahmasb Abad)

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Kerman

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7619813159

Phone
+98 34 3226 3815

Email
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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

Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Dr Javad Darijani

Position
Resercher

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Gharani street, Shahid Bahonar hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Javad Darijani

Position
Researcher

Latest degree

Specialist

Other areas of specialty/work
Emergency Medicine

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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr Javad Darijani

Position
Resercher

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Email
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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
Information about outcome

When the data will become available and for how long
6 month after publish

To whom data/document is available
Researcher

Under which criteria data/document could be used
Any use is permitted for other researchers.

From where data/document is obtainable
Javad Darijani j.darijani@kmu.ac.ir

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

Comments