Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effectiveness of two treatment protocols dexmedetomidine - propofol and midazolam - fentanyl - propofol in relieving pain in patients undergoing lithotomy

Protocol summary

Study aim
Determining the comparison of the efficacy of two treatment protocols, dexmedetomidine-propofol and midazolam-fentanyl-propofol, in relieving pain in patients undergoing surgery

Design
A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 40 patients. The Sealed Envelope website was used for randomization.

Settings and conduct
Subject referral patients in the stone lithotripsy ward of Ganjovian Hospital, Dezful are randomly placed in the group and at the beginning of the study and one week after the start of the study, the level of Substance P is measured and compared with another.

Participants/Inclusion and exclusion criteria
Patients with kidney stones below 2cm and proximal ureter for ESWL aged 18 to 80 years with American Society of Anesthesiologists (ASA) physical status I, II or III who consent to participate in this study will be eligible for this study. Patients who do not agree to participate in this study Patients with chronic liver failure Patients who have a history of allergy to this drug or other alpha-adrenergic drugs Patients with a history of bradycardia and low blood pressure Patients with coagulation disorders Patients with a history of allergy to drugs used to treat ESWL Patients with mental disorders, nervous disorders and skin disorders (inflammation). Patients with active infection Patients who are pregnant Patients who have uremia Patients with BMI>25 Patients who have used painkillers 12 hours before visiting Patients who have pain before visiting

Intervention groups
Intervention group: dexmedetomidine-propofol, control group: midazolam-propofol

Main outcome variables
Plasma level of Substance P in patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230701058625N1**
Registration date: **2023-10-11, 1402/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-11, 1402/07/19**
Update count: **0**

Registration date
2023-10-11, 1402/07/19

Registrant information

Name
Mehdi Rajaeipour

Name of organization / entity

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Iran (Islamic Republic of)

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+98 916 641 0103

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-02, 1402/07/10

Expected recruitment end date
2024-04-12, 1403/01/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of two treatment protocols dexmedetomidine - propofol and midazolam - fentanyl - propofol in relieving pain in patients undergoing lithotomy

Public title
Comparing the effectiveness of two treatment protocols: dexmedetomidine - propofol and midazolam - fentanyl - propofol in relieving pain in patients undergoing extracorporeal stone crusher

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with kidney stones below 2cm and proximal ureter for ESWL aged 18 to 80 years with American Society of Anesthesiologists (ASA) physical status I, II or III who consent to participate in this study will be eligible for this study.
Exclusion criteria:
Patients who do not agree to participate in this study Patients with chronic liver failure Patients who have a history of allergy to this drug or other alpha-adrenergic drugs Patients with a history of bradycardia and low blood pressure Patients with coagulation disorders Patients with a history of allergy to drugs used to treat ESWL Patients with mental disorders, nervous disorders and skin disorders (inflammation). Patients with active infection Patients who are pregnant Patients who have uremia Patients with BMI > 25 Patients who have used painkillers 12 hours before visiting Patients who have pain before visiting

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
40 patients who meet the criteria will enter the study and will be divided into two groups of 20 using computer random numbers. Group A, dexmedetomidine (a vial CC2mcg/200 diluted with CC50 normal saline and infused over 10 minutes.

Blinding (investigator's opinion)
Double blinded

Blinding description
A nurse anesthetist who is not involved in this study will inject the drugs to the patients, then before and three hours after the operation, a blood sample will be taken by the researcher to measure P-Substance. None of the patients, as well as the researcher, will know what medicine was used for each patient.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Dezful University of Medical Sciences
Street address
Justice corner, Post St., 15 Khordad Blvd., Dezful
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Dezfoul
Province
Khouzestan
Postal code
6461669969

Approval date
2023-05-09, 1402/02/19

Ethics committee reference number
IR.DUMS.REC.1402.015

Health conditions studied

1

Description of health condition studied
Patients with Calculus of kidney

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Plasma level of Substance P in patients

Timepoint
At the beginning of the study and one week after lithotomy of the patients

Method of measurement
Measuring the Plasma level with ELISA

2

Description
Pain

Timepoint
At the beginning of the study and one week after lithotomy of the patients

Method of measurement

The person is shown a scale from 0 to 10 and the person gives a score from 0 to 10 on the level of pain felt. (Visual Analogue Scale)

Secondary outcomes

1

Description
Blood pressure
Timepoint
Two times, before ESWL and one week after ESWL
Method of measurement
Manual sphygmomanometer

2

Description
Respiratory rate
Timepoint
Two times, before ESWL and one week after ESWL
Method of measurement
clinical examination

3

Description
Nausea and Vomiting
Timepoint
Two times, before ESWL and one week after ESWL
Method of measurement
Event occur

Intervention groups

1

Description
Intervention group: Group A will receive dexmedetomidine (a vial CC2mcg/200 diluted with CC50 normal saline and infused over 10 minutes. This form of infusion will be repeated if needed) and propofol (0.5 mg/kg)
Category
Treatment - Drugs

2

Description
Intervention group: Group B will receive midazolam (0.025 mg/kg), fentanyl (1 mcg/kg) and propofol (0.5 mg/kg).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dezful Ganjavian Hospital stone crusher department
Full name of responsible person
Mehdi Rajaeipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Dezfoul 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
Dezfoul University of Medical Sciences
Full name of responsible person
Mehdi Rajaeipour

Position
Assistant Professor of Urology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available