Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of two oral drugs clonidine and tramadol on post spinal shivering anesthesia in patients undergoing transureteral lithotripsy (TUL) referred to Shahid Hashemi Nejad hospital in 2016-2017

Protocol summary

Summary

Shivering (Post anesthetic shivering) is a common complication of modern anesthesia and cause complications in the body. The doctor has a duty to keep patient`s body temperature in normal range during surgery. Meperidine is the most widely used drugs for the treatment of PAS.But because of adverse effects, its use has been banned in many medical centers around the world. Many medical studies is ongoing to find a best alternative medicine in this area.In this study, we aimed to compare the effect of oral clonidine and tramadol in preventing post spinal anesthesia shivering. This study is a clinical trial study,80 patients undergoing elective surgery under spinal anesthesia and TUL are being studied And randomly divided into two groups of T and C.Group T receive Tramadol tab 50 mg and group C clonidine tab 100microgram 90 minute before surgery. All patients in terms of temperature and amount of drug and fluid temperatures are in the same condition.Body and tympanic membrane temprachure will be recorded every 10 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031432017N2**
Registration date: **2017-05-20, 1396/02/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Mahmoud Reza Mohaghegh Dolat Abadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

The researcher subscribe the budget because this study costs a little money

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of two oral drugs clonidine and tramadol on post spinal shivering anesthesia in patients undergoing transureteral lithotripsy (TUL) referred to Shahid Hashemi Nejad hospital in 2016-2017

Public title

To evaluate the efficacy of clonidine and tramadol in preventing post spinal anesthesia shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA 1 and 2 patients who underwent

spinal anesthesia for elective TUL. Patients who consent to have spinal anesthesia without any local or general infection, heart disease, bradycardia or left ventricular disfunction, kidney, liver disease, seizures, coagulopathy. Patients with BMI <30 with any history of sensitivity or allergy to clonidine and tramadol or history of addiction. Exclusion criteria: Patients who fail their spinal anesthesia or their spinal anesthesia being off during surgery and underwent general anesthesia or are not satisfied to participate in the study for any reason.

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Besides Milad Tower, Hemmat highway

City
Tehran

Postal code
1449614535

Approval date
2016-05-24, 1395/03/04

Ethics committee reference number
IR.IUMS.REC 1395.9311174020

Health conditions studied

1

Description of health condition studied
Hypothermy due to anaesthesia

ICD-10 code
T88.5

ICD-10 code description
Hypothermy due to anaesthesia

Primary outcomes

1

Description
Peripheral temprature

Timepoint
Every 10 minutes up to 120 min later

Method of measurement
Digital thermometer in Centigrade from forehead

2

Description
Core temprature

Timepoint
Every 10 minutes up to 120 min later

Method of measurement
Digital thermometer in Centigrade from tympanic membrane erea

3

Description
Blood pressure

Timepoint
Every 10 minutes up to 120 min later

Method of measurement
NIBP with digital monitoring in operation room

4

Description
Heart rate

Timepoint
Every 10 minutes up to 120 min later

Method of measurement
With digital monitoring in operation room

5

Description
Shivering

Timepoint
Every 10 minutes up to 120 min later

Method of measurement
Seeing based on Mahajan category

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group oral Clonidine 100 with 50 cc

of water 90 minutes before spinal anesthesia

Category

Treatment - Drugs

2

Description

Second intervention group Tramadol tablets 50 mg orally with 50 cc of water 90 minutes before spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hshemi Nejad hospital

Full name of responsible person

Dr. Mahmood Reza Mohaghegh

Street address

Hashemi Nejad hospital, Vali Nejad Alley, Vali Asr Street, Vanak squere

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahmood Reza mohaghegh

Street address

Hashemi Nejad hospital, ValiNejad alley, Vanak square

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahmood Reza Mohaghegh

Position

Anesthesiologist

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty