

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

+98 912 140 6348

Email address

mohaghegh.mr@moheb.com

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 dysfunction, 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 area

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 square

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

Street address

Hashemi Nejad Hospital, Vali Nejad Alley, Vali Asr street, Vanak square

City

Tehran

Postal code

1969714713

Phone

+98 21 81161

Fax

+98 21 8864 4441

Email

mohaghegh_mr@yahoo.com;
mohaghegh.mr@moheb.com

Web page address

Person responsible for scientific 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

Street address

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Web page address

Person responsible for updating data

Contact

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Iran University of Medical Sciences

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Fax

+98 21 8864 4441

Email

mohaghegh_mr@yahoo.com;
mohaghegh.mr@moheb.com

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