

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of the Effect of Melatonin on Pneumatic Tourniquet Ischemia Reperfusion Injury in Lower Extremity Orthopedic Operation

Protocol summary

Study aim

The Effect of Melatonin on Pneumatic Tourniquet Ischemia Reperfusion Injury in Lower Extremity Orthopedic Operation

Design

A double-blind randomized clinical trial

Settings and conduct

Patients in melatonin group receive 10 mg oral melatonin tablets the night before surgery and 2 hours before surgery and patients in the control group receive placebo orally the night before surgery and 2 hours before surgery. Melatonin and placebo tablets are given by a person who is unaware of the study groups the night before surgery and before the patient enters the operating room. The person who is responsible for collecting the data in the operating room and recovery room was also blinded to the study. Laboratory experts and statisticians responsible for data analysis have also been blinded to the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA Class I, II Age range 18-65 years Patients undergoing lower limb orthopedic surgery using tourniquet Morning schedule. Exclusion criteria: BMI > 30 kg/m², Liver disorders, Patients with severe renal failure, Patients with metabolic acidosis, Patients with congestive heart failure, Blood transfusion, smoking, alcohol consumption, Pregnancy or breastfeeding, Patients taking any anti-oxidant, Drug Allergies, Contraindication of Spinal Anesthesia, Mental disorders which are require drug therapy and analgesics.

Intervention groups

Intervention group: Patients in melatonin group receive 10 mg oral melatonin tablets the night before surgery and 2 hours before surgery. Control group: Patients receive placebo orally the night before surgery and 2 hours before surgery.

Main outcome variables

Serum levels of superoxide dismutase, Serum levels of malondialdehyde, Sedation Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N87**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **prospective**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

Registration date

2019-08-26, 1398/06/04

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effect of Melatonin on Pneumatic Tourniquet Ischemia Reperfusion Injury in Lower Extremity Orthopedic Operation

Public title

The Effect of Melatonin on Pneumatic Tourniquet Ischemia Reperfusion Injury in Lower Extremity Orthopedic Operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA Class I, II Age range 18-65 years Patients undergoing lower limb orthopedic surgery using tourniquet Morning schedule

Exclusion criteria:

BMI > 30 kg/m² Liver disorders Patients with severe renal failure Patients with metabolic acidosis Patients with congestive heart failure Blood transfusion smoking alcohol consumption Pregnancy or breastfeeding Patients taking any anti-oxidant Drug Allergies Contraindication of Spinal Anesthesia Mental disorders which are require drug therapy and analgesics

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to each of the study groups based on the randomization table obtained from Randomization.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

Melatonin and placebo tablets are given by a person who is unaware of the study groups the night before surgery and before the patient enters the operating room. The person who is responsible for collecting the data in the operating room and recovery room was also blinded to the study. Laboratory experts and statisticians responsible for data analysis have also been blinded to the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2019-01-09, 1397/10/19

Ethics committee reference number

IR.SUMS.MED.REC.1397.429

Health conditions studied

1

Description of health condition studied

Orthopedic surgery of the lower extrimites

ICD-10 code

S82.201A

ICD-10 code description

Unspecified fracture of shaft of right tibia, initial encounter for closed fracture

Primary outcomes

1

Description

Serum levels of superoxide dismutase

Timepoint

The night before surgery, pre-medication or placebo are taken immediately before spinal anesthesia and 30 minutes after tourniquet inflation, then 15 minutes after tourniquet removal for measuring superoxide dismutase.

Method of measurement

Enzyme kits

2

Description

Serum levels of malondialdehyde

Timepoint

The night before surgery, pre-medication or placebo are taken immediately before spinal anesthesia and 30 minutes after tourniquet inflation, then 15 minutes

after tourniquet removal for measuring superoxide dismutase.

Method of measurement

Enzyme kits

Secondary outcomes

1

Description

Sedation Score

Timepoint

It is measured before melatonin administration and at intervals of 5,10,20,30,45,60,80 minutes after melatonin administration.

Method of measurement

Ramsey Score

2

Description

Patient satisfaction

Timepoint

At the end of the operation

Method of measurement

Likert criteria

Intervention groups

1

Description

Intervention group: Intervention group: Patients in melatonin group receive 10 mg oral melatonin tablets the night before surgery and 2 hours before surgery.

Category

Prevention

2

Description

Control group: Control group: Patients receive placebo orally the night before surgery and 2 hours before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Sima Razmoji

Street address

Shahid Chamran Hospital, Shahid Chamran Boulevard,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sima Razmjooie

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Reza Jouybar

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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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