

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The effect of melatonin on sedation and tourniquet pain tolerance in intravenous regional anesthesia

Protocol summary

Study aim

The purpose of this study will be to assess the effect of melatonin on sedation and tourniquet pain tolerance in intravenous regional anesthesia.

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2.

Settings and conduct

In Urmia Imam Khomeini hospital operating room after intravenous regional anesthesia the mean arterial pressure, Heart rate, Blood Oxygen Saturation values will be recorded before and immediately after tourniquet inflation, at 10, 20, 30, 40, and 50 min thereafter, and after release of the tourniquet. Assessments of tourniquet-related pain will be performed using visual analog scale immediately after tourniquet inflation and during the surgery. The anesthesiologist will be unaware of which patient will be assigned to which group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 20-60 year: American Society of Anesthesiologists physical status classification I-II :Elective upper limb surgery: Surgery with intravenous regional anesthesia Exclusion criteria: Raynaud's disease: Sickle cell anemia: Chronic pain syndromes: Depression or schizophrenia: Epilepsy: Leukemia: Autoimmune disease: Diabetes: Those who used any analgesic or sedative 24h before surgery: Allergy to any of the study medications: Pregnants :Breast-feeding women

Intervention groups

In the intervention group, patients will be received melatonin (Pharmative LLC USA) 6mg and in control group, patients will be received placebo (Tolid Daru) oral, 90 minutes before the operation.

Main outcome variables

pain: anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N9**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **retrospective**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on sedation and tourniquet pain tolerance in intravenous regional anesthesia

Public title

Evaluation the effect of melatonin on tourniquet pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 20-60 years Patients with American Society of Anesthesiologists (ASA) physical status classification I-II Elective upper limb surgery Surgery with intravenous regional anesthesia

Exclusion criteria:

Raynaud's disease Sickle cell anemia Chronic pain syndromes Depression or schizophrenia Epilepsy Leukemia Autoimmune disease Diabetes Those who used any analgesic or sedative 24h before surgery Those with allergy to any of the study medications Pregnants Breast-feeding women

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups of melatonin 6 mg (group M) and placebo (group P) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware of which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

IR.UMSU.REC.1395.475

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

M79.603

ICD-10 code description

Pain in arm, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Immediately after filling the tourniquet and in minutes 10, 20, 30, 40 and 50 during the surgery

Method of measurement

Verbal Pain Score

2

Description

Anxiety

Timepoint

Immediately after filling the tourniquet and in minutes 10, 20, 30, 40 and 50 during the surgery

Method of measurement

Verbal Anxiety Score

Secondary outcomes

1

Description

Mean arterial pressure

Timepoint

Immediately after filling the tourniquet and in minutes
10, 20, 30, 40 and 50 during the surgery
Method of measurement
None invasive barometer pressure

2

Description

Heart rate

Timepoint

Immediately after filling the tourniquet and in minutes
10, 20, 30, 40 and 50 during the surgery

Method of measurement

Electrocardiogram

3

Description

Arterial oxygen saturation

Timepoint

Immediately after filling the tourniquet and in minutes
10, 20, 30, 40 and 50 during the surgery

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group will be received Melatonin LLC USA
Melatonin, Nature Made/Pharmative 6 mg tablet oral
placebo 90 minutes before surgery.

Category

Treatment - Drugs

2

Description

Control group will be received oral placebo (Tolid daru)
60 minutes before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomeini Hospital, operating room C

Full name of responsible person

Shahryar Sane

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Ershad Avenue, Modarres Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

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