

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison effects of Melatonin premedication on Propofol and induction dose in abdominal surgery

Protocol summary

Study aim

Aim of this study comparison effects of Melatonin premedication on Propofol and induction dose in abdominal surgery

Design

This study is clinical trial and double blind.88 patients candidate abdominal surgery in Valiasr hospital will inter this study.We divided patients in two groups by simple randomization.

Settings and conduct

This study is clinical trial and double blind.88 patients candidate for abdominal surgery entered the study in Valiasr hospital.This study is double blind.Outcome assessor and analyzer are blind (double blind).Outcome assessor and analyzer don't aware from grouping.We divide patients in two groups randomly.We inject 3 milligram Melatonin sublingual50 minute before surgery in intervention group .We inject placebo 50 minute before surgery in control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 15-55 years, non-emergency abdominal surgery, surgery time 30 minutes to 1 hour and a half, body mass index 19 to 25, no drug use during the past week, no use of benzodiazepine-derived drugs over the past 72 hours Exclusion criteria: dissatisfaction

Intervention groups

We inject 3 milligram Melatonin sublingual (Canadian manufacturer Inter natural - 3 milligrams) 50 minute before surgery in intervention group (volume is brought to 3 milliliter).We inject placebo 50 minute before surgery in control group (volume is brought to 3 milliliter).

Main outcome variables

Anxiety, awareness, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N98**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of Melatonin premedication on Propofol and induction dose in abdominal surgery

Public title

Comparison effects of Melatonin premedication on Propofol and induction dose in abdominal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

15-55 years Non-emergency abdominal surgery Surgery time 30 minutes to 1 hour and a half body mass index 19 to 25 No drug use during the past week No use of benzodiazepine-derived drugs over the past 72 hours

Exclusion criteria:

Dissatisfaction

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number in division of groups in two groups A and B. Patients are divide in two groups randomly. The random sequence is parallel. Randomization method: Simple randomization. Random unit: Individual. Randomization Tool: Random Number Tables. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Outcome assessor and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. Outcome assessor isn't aware of grouping. Analyzer and outcome assessor know the groups in the form A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-02-27, 1395/12/09

Ethics committee reference number

IR.ARAKMU.REC.1395.432

Health conditions studied

1

Description of health condition studied

abdominal surgery

ICD-10 code

R40.4

ICD-10 code description

Transient alteration of awareness

Primary outcomes

1

Description

Anxiety

Timepoint

before and after intervention

Method of measurement

Visual analog scale

2

Description

Awareness

Timepoint

before and after intervention

Method of measurement

Visual analog scale

3

Description

sedation

Timepoint

before and after intervention

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We inject 3 milligram Melatonin sublingual (Canadian manufacturer Inter natural - 3 milligrams) 50 minute before surgery (volume is brought to 3 milliliter).

Category

Treatment - Drugs

2

Description

control group: We inject placebo 50 minute before surgery (volume is brought to 3 milliliter).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Afsaneh Norouzi

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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valiasr.hospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Shahin Fateh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Afsaneh Noruzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Leila Akrami

Position

resident of anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Afsaneh Norouzi

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments