

# 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

#### City

Arak

#### Province

Markazi

#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Fax

+98 86 3222 2003

#### Email

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

#### City

Arak

### Province

Markazi

### Postal code

3814957558

### Phone

+98 86 3222 2003

### Email

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

#### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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#### Province

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#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Fax

#### Email

sh.fateh@arakkmu.ac.ir

#### 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

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

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**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3471 3638

**Fax**

**Email**

dr.noruzi@arakmu.ac.ir

**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

**Street address**

Payambar Azam Complex, Basij square, Sardasht

**City**

Arak

**Province**

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**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

akrami@gmail.com

**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**