

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 2026

### Investigating the effect of melatonin on reducing preoperative anxiety in abdominal hysterectomy; a double blinded clinical trial study

#### Protocol summary

##### Study aim

Determining the effect of melatonin on preoperative anxiety in hysterectomy surgery

##### Design

A double-blinded, randomized clinical trial, phase 3 with parallel groups, that includes a control group, design of 80 patients.

##### Settings and conduct

This clinical trial will be done in Alzahra Hospital in Rasht, on patients candidate for hysterectomy. 80 patients randomly and with quadruple block method will be divided in two groups of receiving lorazepam + melatonin and lorazepam + sugar water. After receiving the drug, patients will be transferred to the recovery room and monitored to control Blood pressure and heart rate. The basis for comparing these two groups is Visual Analogue Scale. We will measure three times in this study: Before Prescribing the drug, when patients enter the operating room and before the anesthetic induction. Finally, the data will be compared in the two groups. In this study, patients, the responsible anesthesiologist, and the information collector are BLIND.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for elective abdominal hysterectomy, Aged 30-65. Exclusion criteria: Major surgery in the past three years. Chronic health problems. Mood disorders (anxiety). Addiction.

##### Intervention groups

Intervention group: Lorazepam( manufacturer company: Abidi) 1 milligram given at the preoperative night+ 6 milligrams of melatonin( 2 pills of 3 milligrams, manufacturer company: Aristo) 90 minutes before operation dissolved in 20 milliliters of water + 2 sugar loaves. Control group: Lorazepam 1 milligram in the preoperative night( manufacturer company: Abidi) + 90 minutes before operation 20 milliliters of water + 2 sugar loaves. based on the hospital routine, all patients candidate for hysterectomy will be given lorazepam 1miligramms, preoperative night, (as a sedative).

#### Main outcome variables

Preoperative anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100707004345N6**

Registration date: **2019-04-11, 1398/01/22**

Registration timing: **prospective**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

##### Registration date

2019-04-11, 1398/01/22

##### Registrant information

##### Name

Ali Mirmansouri

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1666 9064

##### Email address

a\_mirmansoori@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-05, 1398/02/15

##### Expected recruitment end date

2019-07-06, 1398/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of melatonin on reducing preoperative anxiety in abdominal hysterectomy; a double blinded clinical trial study

**Public title**  
The effect of melatonin on anxiety before hysterectomy

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Candidate for elective abdominal hysterectomy Aged 30-65  
**Exclusion criteria:**  
Major surgery for the past three years Chronic health problems like diabetes, cardiovascular disease Mood disorders (anxiety) that are under medication Addiction Malignant problems that cause hysterectomy Emergency hysterectomy

**Age**  
From **30 years** old to **65 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
To produce random sequences in this clinical trial, we will use this site:  
<http://www.graphpad.com/quickcalcs/index.cfm>. A nurse who is not in the study, 90 minutes before surgery, will randomly divide patients into two groups by quadruple block method that includes: lorazepam + melatonin( dissolved in 20 milliliters sugar water) group and lorazepam+ sugar water group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
A nurse who is not in the study randomly will divide patients into two groups and 90 minutes before surgery, for the intervention group, she will dissolve two melatonin pills in 20 milliliters of water. 2 sugar loaves will be added to it for not determining the taste. In the Control group, the same amount of sugar water is prescribed. After receiving the drug, the patient will be transferred to the recovery room and will be monitored to control blood pressure and heart rate. In this study, patients, the responsible anesthesiologist, and the information collector are BLIND.

**Placebo**

Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee Of Guilan University Of Medical Sciences  
**Street address**  
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4144666949

**Approval date**  
2019-03-16, 1397/12/25

**Ethics committee reference number**  
IR.GUMS.REC.1397.528

## Health conditions studied

**1**

**Description of health condition studied**  
Anxiety before abdominal hysterectomy surgery

**ICD-10 code**  
F43

**ICD-10 code description**  
Reaction to severe stress and adjustment disorders

## Primary outcomes

**1**

**Description**  
Patient's anxiety before surgery

**Timepoint**  
Before prescribing the drug, when patients enter the operating room and before the anesthetic induction

**Method of measurement**  
Visual Aualogue scale

## Secondary outcomes

**1**

**Description**  
Blood pressure

**Timepoint**

Before prescribing the drug, when patients enter the operating room and before the anesthetic induction

**Method of measurement**  
Manometer

## 2

**Description**

Heart rate

**Timepoint**

Before prescribing the drug, when patients enter the operating room and before the anesthetic induction

**Method of measurement**

Monitoring

## **Intervention groups**

### 1

**Description**

Intervention group: The group receiving lorazepam + Melatonin: Dosage of Melatonin for patients will be 6 milligrams based on previous studies. (3 milligrams tablets are available on the market, so two tablets are considered).(manufacturing Company: Aristo ).As the routine of this hospital is to prescribe 1miligramm lorazepam( manufacturing Company: Abidi)preoperative night for all patients candidate for hysterectomy, so both groups will receive this amount of lorazepam. (This treatment alone did not control anxiety in patients.)90 minutes Prior to surgery, a nurse who is not in the study will dissolve melatonin pills in 20 milliliters of water and will add 2 sugar loaves in order to not determine its taste.

**Category**

Prevention

### 2

**Description**

Control group: The group receiving lorazepam + sugar water: preoperative night 1miligramm lorazepam( manufacturing Company: Abidi) will be given to patients.90 minutes prior to surgery,2 sugar loaves will be dissolved in 20 milliliters of water and it will be given to the patient by a nurse who is not in the study.

**Category**

Prevention

## **Recruitment centers**

### 1

**Recruitment center**

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Dr Ali Mirmansouri

**Street address**

Opposite Shahid Azodi Stadium,Namjoo Street

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## **Sponsors / Funding sources**

### 1

**Sponsor**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Doctor Shadman Nemati

**Street address**

Vice Chancellor for research of Guilan,Shahid Siadati Avenue, Namjoo Street

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drshadmannemati\_ent@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rasht 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**

Rasht University of Medical Sciences

**Full name of responsible person**

Ali Mirmansouri

**Position**

Associate Professor of Cardiac Anesthesiology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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Heshmat Hospital, at the beginning of bayani street,  
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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Mohadese Ahmadi

**Position**

Research Expert/(MSc) English

**Latest degree**

Master

**Other areas of specialty/work**

Research Expert

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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