

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Assessment on the effect of Melatonin on Pain control after Abdominal Hystrectomy

Protocol summary

Summary

As the human studies on the effect of Melatonin" as an adjuvant drug" has been restricted, and contradictory. And it has been known pain perception is multifactoria, we decided to compare the effect of preventive doses of Melatonin and Pregabalin in patients who will be candidated for abdominal hysterectomy under general anesthesia. The study will be a randomized double blinded clinical trial. After taking the confirmation from research and ethical committee of Guilan University , and consent inform from patients, 20 cases in ASA I, II , between 35-55 years old will be put into the study. The day before the TAH, patients educated by one of the members about method of study and drug administration and adverse effects. Method of pain assessment(Numerical Rating Scale"0-10") at 1,6,12,24th after the surgery, will be explained to patients. The night before the TAH, cases will be divided into 3 groups;1)Melatonin, 2)Pregabalin, 3)Control group. Anesthetic method will be the same in all 3 groups. Patient monitoring performed with SaO2, ECG, CO2 monitoring and Blood Pressure control. Blood Clot (5 cc)will be taken just before and after the operations. Pain intensity should be assessed with NRS scoring(0-10). Post operative pain control will be alleviate with Fentanil(NRS>4). All medical side effects will be assessed. Ondansetron will be prescribed in consider to Nausea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090816325N3**

Registration date: **2015-12-09, 1394/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-09, 1394/09/18

Registrant information

Name

Katayoun Haryalchi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

haryalchi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research-Guilan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment on the effect of Melatonin on Pain control after Abdominal Hystrectomy

Public title

Assessment on the effect of Melatonin on Pain control after Abdominal Hystrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Total Abdominal Hysterectomy; Age 35-55; ASA I, II
Exclusion criteria: Patients in consideration of Cardiac; Pulmonary; hepatic; Renal; autoimmune; psychological; gastrointestinal diseases; Diabetes; sleep disorders; Epilepsy; Nystagmus; Leukemia; speech and hearing disorders; seasonal and drug allergies; chronic analgesia; hypnotics; psychotropic; opioid; Beta blockers and MAOI consumption; adverse drug reactions; patients refuse to collaborate.

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Vice Chancellor for Research-Guilan University of Medical Sciences

City

Rasht

Postal code

Approval date

2015-08-24, 1394/06/02

Ethics committee reference number

IR.GUMS.REC.1394.230

Health conditions studied

1

Description of health condition studied

Pain after abdominal hysterectomy

ICD-10 code

N99.9

ICD-10 code description

Postprocedural disorder of genitourinary system, unspecified

Primary outcomes

1

Description

Pregabalin(50 mg) with a glass of water

Timepoint

Two hours before the surgery

Method of measurement

mg/kg

2

Description

Melatonin

Timepoint

Two hours before the surgery

Method of measurement

Mg/kg

3

Description

Fentanyl

Timepoint

Hours(1-6-12-24)

Method of measurement

µg/kg

Secondary outcomes

1

Description

Intensity of pain

Timepoint

During first hour after the

Method of measurement

surgery

2

Description

Serum Melatonin

Timepoint

During first hour after the surgery

Method of measurement

pg/mL

3

Description

Serum Beta Endorphin

Timepoint

During first hour after the surgery

Method of measurement

ng/L

Intervention groups

1

Description

No prescription 2 hours before the TAH in control group

Category

Treatment - Drugs

2

Description

Melatonin Tablet(5 mg) prescription 2 hours before the TAH in intervention group

Category

Treatment - Drugs

3

Description

Pregabalin Capsule(50 mg) prescription 2 hours before the TAH in intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

KatayounHaryalchi

Street address

Alzahra Hospital- Namjoo Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research-Guilan University of Medical Sciences

Full name of responsible person

Dr. A. Heidarzade

Street address

Vice Chancellor for Research-Guilan University of Medical Sciences Namjoo Street

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research-Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan university of Medical Sciences

Full name of responsible person

Dr.Katayoun Haryalchi

Position

Assistant Professor of Guilan university of Medical Sciences

Other areas of specialty/work

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Rasht, Namjo street, Alzahra hospital, Reproductive Health Research Center

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor of Guilan University of Medical Sciences

Other areas of specialty/work

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Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

B.S.Midwife

Other areas of specialty/work**Street address**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty