

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

An assessment about impression of oral Methylnaltrexone on time of beginning of the bowel sounds after abdominal hysterectomy

Protocol summary

Summary

This is a randomized double blind clinical trial for assessment the impression of oral Methylnaltrexone on time of beginning of the bowel sounds after abdominal hysterectomy. Inclusion criteria are: women who are 35 till 55years old (with ASA class I&II) without history of susceptible diseases for post-operative nausea and vomiting; not having chronic constipation, IBS and IBD; no history of drug allergies; addiction to opioids; no history of renal, hepatic or respiratory diseases; no history of twice laparotomy or more or organ transplantation. Exclusion criteria are: duration of operation more than two hours; other operation accompany by hysterectomy; incidence of operation's or anesthesia's side-effects and patients that have hypertension. Sixty six women are randomly assigned into the two groups. Subjects will receive either oral Methylnaltrexone or placebo two hours before operation. All of the study participants will receive general anesthesia with same medications and undergo to the operation by one gynecologist. After operation and stable vital signs, their bowel sounds in 12, 13, 14, ... 23,24 hours after operation will be listened every hour for one minute in right lower quadrant of abdomen by one person and other measurements will check one by one.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104121946N8**

Registration date: **2011-09-13, 1390/06/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-09-13, 1390/06/22

Registrant information

Name

Mandana Mansur Ghanaie

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

m_m_ghanaie@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research-Guilan University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An assessment about impression of oral Methylnaltrexone on time of beginning of the bowel sounds after abdominal hysterectomy

Public title

An assessment about impression of oral Methylnaltrexone on time of beginning of the bowel sounds after abdominal hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1) women who were 35-55 years old (with ASA class I&II) .2) without history of susceptible diseases for post-operative nausea and vomiting for example peptic ulcer, gastritis and uses of chemotherapy's drugs. 3) Lack of history about chronic constipation , IBS and IBD. 4) Without history of drug reaction to Naltrexone , another drugs, foods and seasonal allergies or asthma. 5) Lack of kidney's diseases.6) lack of liver's diseases especially hepatitis. 7) lack of addiction to opioids (Tramadol, Morphine, Percocet) and alcohol.8) lack of using psychological drugs/pain reliefer with Codeine or Propoxyphene/ Clonidine/ Disulfiram/ Laxative/ Immunosuppress drugs/ thyroglobulin for diagnose Hashimoto's thyroiditis or hypothyroidism.9) Without history for laparotomy twice or more than. 10) lack of lung's diseases. 11) Without history of organ's transplantation. Exclusion criteria: 1) duration of operation more than two hours.2) existence of another operation accompanied by hysterectomy.3) incidence of operation's or anesthesia's side-effects.4) hypertension.

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: **66**

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

Vice chancellor for research-Guilan University of Medical Sciences

Street address

Vice chancellor for research-opposite of Azodi Studium-Namjo street

City

Rasht

Postal code

Approval date

2011-05-28, 1390/03/07

Ethics committee reference number

1900136005

Health conditions studied

1

Description of health condition studied

Postprocedural disorders of genitourinary system, not elsewhere classified

ICD-10 code

N99

ICD-10 code description

Postprocedural disorder of genitourinary system, unspecified

Primary outcomes

1

Description

An assessment about impression of oral Methylnaltrexone on time of beginning of the bowel sounds after abdominal hysterectomy

Timepoint

12 hours after operation, every hour

Method of measurement

Patient visits, listening to bowel sounds

Secondary outcomes

1

Description

Assessment of median time of beginning of the bowel sounds

Timepoint

Assessment of median time of beginning of the bowel sounds in first group (patients that received oral Methylnaltrexone)

Method of measurement

Patient visits, listening to bowel sounds

2

Description

Determination of frequency of urinary retention

Timepoint

After fully discharge

Method of measurement

Assessment about patient's ability to urinating

3

Description

Determination of frequency of constipation

Timepoint

after surgery

Method of measurement

Patient visits, question about defecation

4

Description

Determination of frequency of vomiting

Timepoint

after surgery

Method of measurement

Patient visits, question about vomiting

5

Description

Determination of frequency of itching

Timepoint

after surgery

Method of measurement

Patient visits, question on base of itching score

6

Description

Determination of frequency of ileus

Timepoint

12 hours after operation, every hour

Method of measurement

Patient visits, listening to bowel sounds

7

Description

Determination of frequency of side-effects (abdominal pain, bloating ,nausea ,hyperthermia, vertigo ,hypotension)

Timepoint

after surgery

Method of measurement

Patient visit and examine

Intervention groups

1

Description

Intervention group: Oral Methylnaltrexone tablet (25mg); two hours before operation. After operation, bowel sounds in 12,13,...,23,24 hours were listened every hour for one minute in right lower quaderant of abdomen and other measurements were checked.

Category

Treatment - Drugs

2

Description

Control group: Placebo oral tablet (25mg); two hours before operation. After operation, bowel sounds in 12,13,...,23,24 hours were listened every hour for one minute in right lower quaderant of abdomen and other measurements were checked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital, Rasht

Full name of responsible person

Street address

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. Abdolrasol Sobhani

Street address

Vice Chancellor for research,Namjoo Ave.

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. Mandana Mansur Ghanaie

Position

Associate professor of Guilan University of Medical Sciences

Other areas of specialty/work

Street address

Reproductive Health research center-Alzahra hospital-Namjo street

City

Rasht

Postal code
Phone
+98 13 1322 5624
Fax
Email
m_m_ghanaie@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr. Mandana Mansur Ghanaie
Position
Associate professor of Guilan University of Medical Sciences
Other areas of specialty/work
Street address
Reproductive Health research center-Alzahra hospital-
Namjo street
City
Rasht
Postal code
Phone
+98 911 131 3242
Fax
Email
m_m_ghanaie@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Reproductive Health research center
Full name of responsible person
seyedeh Fatemeh Dalil Heirati
Position
B.S
Other areas of specialty/work
Street address
Reproductive Health research center-Alzahra hospital-
Namjo street
City
Postal code
Phone
Fax
Email
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