Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Postoperative pain control by topical subcutaneous analgesic injection at the end of surgery

Protocol summary

Study aim
Evaluation of the effect of pain control after surgery using local analgesic agents that are injected at the site of incision at the end of the operation

Design
Two arm parallel group randomized clinical trial with blinded outcome assessment, randomized groups on 100 patients using the envelope method

Settings and conduct
This study will be performed in Ghaem Hospital in Mashhad on 100 patients with inclusion criteria who undergo laparotomy with midline incision with an operation time of 60 to 90 minutes. After closing the fascia and before closing the skin in the intervention group, 1-1.5 cc/CM of incision from 0.2% rupivacaine solution will be injected subcutaneous. The patient and the nurse will be unaware . Patients' pain during the 2, 6, 12 and 24 hours after surgery will be assessed with visual analog scale instrument.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 40-60 years with BMI = 25-30 without previous history of laparotomy with ovarian mass with ultrasound, CT scan (solid cystic masses, papillary projection, abdominal ascites, parietal nodules, etc.) and tumor marker based on malignancy (High levels of markers CA125 and CEA) who are admitted to the gynecological oncology ward of Ghaem Hospital and undergo laparotomy with midline incision with an average operation time of 60 to 90 minutes in the central operating room of the hospital are included in the study. Exclusion criteria: History of severe heart disease, anemia, liver disease, kidney disease, anesthetic allergy, history of hypotension or hypertension

Intervention groups
In the intervention group, at the end of surgery, 0.2% of topical rupivacaine is injected in the subcutaneous area at the rate of 1 to 2 cc per centimeter of incision.

Main outcome variables
Patient pain control after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220108053667N1**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information

Name
Maryam Esmaeilpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3866 2557

Email address
mrm.esmaeilpour@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-08, 1400/10/18

Expected recruitment end date
2023-07-09, 1402/04/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Postoperative pain control by topical subcutaneous analgesic injection at the end of surgery

Public title
Postoperative pain control by topical subcutaneous analgesic injection at the end of surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 40-60 years BMI = 25-30 without previous history of laparotomy ovarian mass with ultrasound, CT scan (solid cystic masses, papillary projection, abdominal ascites, parietal nodules, etc.) and tumor marker based on malignancy (High levels of markers CA125 and CEA) laparotomy with midline incision average operation time of 60 to 90 minutes
Exclusion criteria:
History of severe heart disease anemia liver disease kidney disease anesthetic allergy history of hypotension or hypertension
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study uses from simple randomization using opaque SNOSE sealed envelopes (sequentially numbered, opaque, sealed envelopes). In this way, the letters A and B are prepared and printed by one of the team members and placed inside the envelope. The envelope closes and its contents are not visible from outside. Then, the purpose of the study is explained to the person who has the conditions, and the person, if desired, signs the informed consent form and takes an envelope, and then opens it and based on the contents of the envelope in the intervention group (A) or control (B) enters.
Blinding (investigator's opinion)
Single blinded
Blinding description
The specialist physician divides the patients into two groups based on a random method and injects analgesic agents subcutaneously at the end of surgery in the intervention group . 2,6,12,24 hours after the operation, the patient's pain in the ward is assessed and recorded by the nurse based on the vas. The nurse who evaluates the patients' pain in the ward and the doctor who completes the questionnaire are not aware of the prescribed treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Gynecology department, Ghaem hospital, Ahmad Abad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9187145785
Approval date
2021-12-14, 1400/09/23
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.621

Health conditions studied

1

Description of health condition studied
Pain control after surgery for ovarian malignancies
ICD-10 code
C56
ICD-10 code description
Malignant neoplasm of ovary

Primary outcomes

1

Description
Pain score of patients after surgery
Timepoint
2, 6, 12 and 24 hours after surgery
Method of measurement
Patients' pain is measured based on Visual Analog Scale

Secondary outcomes

1

Description
Recurrence of intestinal function
Timepoint
12 and 24 hours after surgery
Method of measurement
Questions from the patient and patient file information

2

Description
Opioid use to control pain
Timepoint
2,6,12,24 hours post operation
Method of measurement
patient file information

3

Description
Diclofenac suppository and acetaminophen injection for pain control
Timepoint
2,6,12,24 hours post operation
Method of measurement
patient file information

Intervention groups

1

Description
Intervention group: In the intervention group, at the end of surgery, before closing the skin in the subcutaneous area, 0.2% topical ropivacaine is injected at the rate of 1 to 2 cc per centimeter of incision.
Category
Treatment - Drugs

2

Description
Control group: In this group, subcutaneous injection is not performed at the end of surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital of Mashhad
Full name of responsible person
Marjaneh Farazestanian
Street address
Ahmad Abad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176999311
Phone
+98 51 3840 0000
Email
FarazestanianM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Marjaneh Farazestanian
Street address
Gynecology department, Ghaem hospital, Ahmad Abad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176999311
Phone
+98 51 3840 0000
Email
farazesmanianm@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Marjaneh Farazestanian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Gynecology department, Ghaem hospital, Ahmad Abad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code

9176999311

Phone
+98 51 3840 0000

Email
FarazestanianM@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Esmaeilpour

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Gynecology department, Ghaem hospital, Ahmad Abad Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
9176999311

Phone
+98 51 3840 0000

Email
esmailpoorm2@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Esmaeilpour

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Gynecology department, Ghaem hospital, Ahmad Abad Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
9176999311

Phone
+98 51 3840 0000

Email
esmailpoorm2@yahoo.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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
6 months after the publication of the results

To whom data/document is available
For researchers working in academic institutions

Under which criteria data/document could be used
The results and documentation of the study can also be used by experts outside of academic centers

From where data/document is obtainable
Email the person in charge of the scientific respondent. Dr. Maryam Esmaeilpour esmailpoorm2@yahoo.com

What processes are involved for a request to access data/document
Request the following email address to send the information within a week. esmailpoorm2@yahoo.com

Comments