Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

"Investigation of the effect of intraperitoneal dexamethasone on pain after gynecological laparoscopic surgery"

Protocol summary

Study aim
Investigation of intraperitoneal dexamethasone administration on reducing the severity of pain and reducing the frequency of drug administration after gynecological laparoscopic surgery

Design
A clinical trial with a control group, with parallel, two-way, blind, randomized groups, was performed on 70 patients who were divided into two equal groups of drugs and placebo according to the table of random numbers

Settings and conduct
Candidates for laparoscopic gynecological surgery at Shahid Sadoughi Hospital, entered the study in two groups. Patients were divided into two equal groups of drugs and placebo using a table of random numbers. In the first group, 20 cc of normal saline was injected, and in the second group, 20 cc of normal saline containing 16 mg dexamethasone was injected into the peritoneal cavity. Postoperative pain information was recorded in a questionnaire using the VAS criterion.

Participants/Inclusion and exclusion criteria
70 patients with ASA class 1 and 2; aged 18-70 candidates for gynecological laparoscopic surgery for myomectomy; BMI is more than 30; diabetes or other underlying disease; abdominal surgery as well as a history of chronic; taking antinauseant drugs and vomiting 48 hours before surgery; long-term use of painkillers addiction; sensitivity to anesthetics and dexamethasone.

Intervention groups
Patients were divided into two equal groups using random number tables It should be noted that the drug and placebo were already prepared and coded in 20 cc syringes In the first group, after cesarean section and before leaving the trocar 20 cc of normal saline was sprayed in the diaphragm and peritoneal cavity In the second group after surgery and before leaving the trocar 20 cc of normal saline containing 16 mg dexamethasone was sprayed in the diaphragm and peritoneal cavity

Main outcome variables
Reduce pain and reduce the need for narcotics after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200424047191N1**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **retrospective**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date
2020-06-18, 1399/03/29

Registrant information

Name
Fahimeh Dehghan Dehnavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3836 1465

Email address
fatemahdehghan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-22, 1397/06/31

Expected recruitment end date
2019-03-19, 1397/12/28

Actual recruitment start date
2018-09-21, 1397/06/30

Actual recruitment end date

2019-03-18, 1397/12/27

Trial completion date

2019-03-18, 1397/12/27

Scientific title

"Investigation of the effect of intraperitoneal dexamethasone on pain after gynecological laparoscopic surgery"

Public title

"Investigation of the effect dexamethasone on pain after gynecological laparoscopic surgery"

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

70 female patients with ASA class 1 and 2 Age range of 18 to 70 years old Candidates for elective surgery by gynecological laparoscopy to apply myomectomy in Shahid Sadoughi Hospital Completing the written consent form

Exclusion criteria:

BMI over 30 Diabetes or other underlying disease Abdominal surgery as well as a history of chronic pain Taking anti nausea drugs and vomiting 48 hours before surgery is a long-term use of painkillers, addiction, sensitivity to anesthetics and dexamethasone.

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two equal groups of drugs and placebo using the simple random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person following the patient and filling out the questionnaire do not know any of the drugs used (dexamethasone or placebo)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Yazd-International Branch of Shahid Sadoughi University of Medical Sciences

City

Yazd

Province

Yazd

Postal code

8944158318

Approval date

2018-01-09, 1396/10/19

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.227

Health conditions studied

1

Description of health condition studied

Pain after myomectomy after laparoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dexamethasone side effects include: hyperglycemia, dizziness and headache and tinnitus

Timepoint

After surgery

Method of measurement

Questionnaire

2

Description

Shoulder pain after surgery The scoring system is based on the Visual Analogue Scale system so that we can explain to the patient that 0 means no pain and 10 means the most pain is tolerable.

Timepoint

After surgery

Method of measurement

Questionnaire

3

Description

Abdominal pain after surgery. The scoring system is based on the Visual Analogue Scale system so that we can explain to the patient that 0 means no pain and 10 means the most pain is tolerable.

Timepoint
After surgery

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, normal saline containing 16 mg of dexamethasone is sprayed into the diaphragm and peritoneal cavity after surgery and before leaving the trocar

Category
Treatment - Drugs

2

Description
Control group: After surgery and before leaving the trocar, 20 cc of normal saline is sprayed in the diaphragm and peritoneal cavity

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital

Full name of responsible person
Dr. Atiye Javaheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Masoud Mirzaei

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Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Dr Atiye Javaheri

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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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