Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of dexamethasone versus ketorolac on postoperative analgesia and side-effects of minor laparoscopic surgeries: a double-blinded randomized clinical trial

Protocol summary

Study aim

To compare the effect of dexamethasone and ketorolac on postoperative analgesia and side-effects in minor laparoscopic surgeries

Design

Randomized controlled clinical trial, three-arm parallel-group design of 114 patients, double-blinded. Randomization will be done by the rand function of Excel software.

Settings and conduct

Patients who are referred to the Arash Women's Hospital of Tehran University of Medical Sciences, if eligible, will be randomized into the three study groups including ketorolac, dexamethasone, and placebo. The participants, injectors, and outcome assessors will be blinded to the group assignment.

Participants/Inclusion and exclusion criteria

Patients who are elected for minor laparoscopic surgeries (diagnostic laparoscopy, cystectomy, salpingectomy, oophorectomy, and tubectomy) would be evaluated for the study eligibility criteria. Inclusion criteria are the age of 18-65 years, body mass index <30 kg/m2, and American Society of Anesthesiologists grade I or II. Exclusion criteria are allergy to analgesics, anticoagulant consumption during the last four weeks, daily intake of opioids or anti-anxiety medications, fever, or bacterial infection within the last two weeks

Intervention groups

Participants will be allocated to the three study groups, 38 patients each. The study includes two intervention groups (dexamethasone and ketorolac) and one control group (placebo). The first group will receive 30 mg intravenous ketorolac (15 mg/ml, 2 ml). The second group will receive 8 mg intravenous dexamethasone (4 mg/ml, 2 ml). The third group (placebo group) will receive 2 ml intravenous normal saline.

Main outcome variables

Postoperative pain, postoperative opioid consumption, postoperative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006640N7**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name
Zahra Asgari
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of dexamethasone versus ketorolac on postoperative analgesia and side-effects of minor laparoscopic surgeries: a double-blinded randomized clinical trial

Public title
Comparison of the efficacy of dexamethasone versus ketorolac on postoperative analgesia and side-effects of minor laparoscopic surgeries
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18-65 years Body mass index <30 kg/m2 American Society of Anesthesiologists grade I or II
Exclusion criteria:
Allergy to analgesics Anticoagulant consumption during the last four weeks before the surgery Daily intake of opioids or anti-anxiety medications Fever Bacterial infection within the last two weeks before the surgery
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization approach will be implemented in this study. Randomization will be performed using a computer-generated list. For this purpose, 114 sealed envelopes will be numbered 1-114 according to the randomization list. Group allocation will be kept separate until the study is completed. The randomization ratio would be 1: 1, with 38 envelopes allocated to each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
A nurse that is not involved in the study opened a sealed envelope in a closed medicine room 30–60 min before the operation. According to the envelope code, the analgesics or placebo were drawn into a 2-ml syringe and intravenously injected into the participants. All solutions are transparent and visually similar.Therefore, both injectors and recipients were kept blinded to the group allocation. Outcome assessors will be kept blinded from the patients' allocation, as well.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciencse
Street address
Arash Women Hospital, Corner of 162 Alley (Shahid Abdolmajid), Next Police Station 126, Shahid Baghdarnia St. (North Rashid), after Shahid Bagheri Highway, Resalat Highway.
City
Tehran
Province
Tehran
Postal code
1598116539
Approval date
2020-02-20, 1398/12/01
Ethics committee reference number
IR.TUMS.Medicine.REC.1398.942

Health conditions studied

1

Description of health condition studied
Post-laparoscopic pain, number of post-laparoscopic opioid consumption, post-laparoscopic nausea and vomiting.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post-laparoscopic pain
Timepoint
1, 6, 12, and 24 hours after the laparoscopy
Method of measurement
Visual analog scale

2

Description
Opioid consumption
Timepoint
Within 24 hours after laparoscopy

Method of measurement
Recorded number in the patients' medical profile

Secondary outcomes

1

Description
Post-laparoscopic nausea and vomiting
Timepoint
Within 24 hours after the surgery
Method of measurement
Patient's profile

Intervention groups

1

Description
First intervention group: 30 mg intravenous ketorolac (15 mg/ml, 2 ml) 30 min before the surgery
Category
Treatment - Drugs

2

Description
Second intervention group: 8 mg intravenous dexamethasone (4 mg/ml, 2 ml) 30 min before the surgery
Category
Treatment - Drugs

3

Description
Control group: 2 ml intravenous normal saline 30 min before the surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women Hospital
Full name of responsible person
Zahra Asgari
Street address
Arash Women Hospital, Corner of 162 Alley (Shahid Abdolmajid), Next to Police Station 126, Shahid Baghdarnia Street (North Rashid), After Shahid Bagheri Highway, Resalat Highway.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
Central Campus of Tehran University Vice Chancellor for Research, 16 Azar St, Enghelab St.
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1417614411
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zahra Asgari
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Women Hospital, Corner of 162 Alley (Shahid Abdolmajid), Next to Police Station 126, Shahid Baghdarnia Street (North Rashid), After Shahid

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Person responsible for scientific inquiries

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Position
Fellowship

Latest degree
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Gynecology and Obstetrics

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Person responsible for updating data

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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the potential data sets are sharable after anonymizing.

When the data will become available and for how long
Starting 6 months after publication.

To whom data/document is available
Only available for people working in academic institutions.

Under which criteria data/document could be used
All types of analyses of the data sets are allowed.

From where data/document is obtainable
Doctor Zahra Asgari Tel: 0098 21 9133588917 Email: asgariza@sina.tums.ac.ir

What processes are involved for a request to access data/document
The applicant submits his / her application via email to the responsible researcher and after identification, the requested information will be sent within one month.

Comments