

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Intraperitoneal dexamethasone as a new method for relieving postoperative shoulder pain after gynecologic laparoscopy

Protocol summary

Summary

In this double-blind randomized clinical trial study, we try to show the efficacy of Intraperitoneal dexamethasone on relieving shoulder pain after gynecologic laparoscopy. Our study population will be 18-70 years old women who has been referred to Arash Hospital with an gynecology indication for laparoscopy. Patients with diabetes, previous abdominal surgery and reaction to dexamethasone will be excluded. We randomly divide 63 patients into two groups: first group including 31 patients as dexamethasone group and second group including 32 patients as control (placebo) group. First group receive 16 mg dexamethasone intraperitoneally at the end of procedure whereas control group will receive 16 mg normal saline as placebo intraperitoneally, at the end of procedure. Visual analogue scale (VAS) will be used for clinical evaluation of pain severity during 24 hours after laparoscopy . A physician, who is not aware from treatment or placebo will evaluate the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105306640N1**

Registration date: **2011-09-01, 1390/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-01, 1390/06/10

Registrant information

Name

Zahra Asgari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 8755

Email address

asgariza@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Arash Hospital

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2010-12-29, 1389/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intraperitoneal dexamethasone as a new method for relieving postoperative shoulder pain after gynecologic laparoscopy

Public title

Intraperitoneal dexamethasone as a new method for relieving postoperative shoulder pain after gynecologic laparoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female; 18 -70 years old; gynecologic indication for laparoscopy. Exclusion criteria: previous surgery on their abdomen; diabetes mellitus; drug reaction to dexamethasone; previous history of treatment with steroids.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **63**

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Science, Enghelab square

City

Tehran

Postal code**Approval date**

2011-07-23, 1390/05/01

Ethics committee reference number

90/d/130/593

Health conditions studied**1****Description of health condition studied**

shoulder pain after gynecologic laparoscopy

ICD-10 code

R52.9

ICD-10 code description

Pain, unspecified

Primary outcomes**1****Description**

pain

Timepoint

4,8,12,24 hours after procedure

Method of measurement

Visual Analog Scale (VAS) scale

Secondary outcomes

empty

Intervention groups**1****Description**

intervention: we will inject 16 cc dexamethasone intraperitoneally in case group at the end of laparoscopy.

Category

Treatment - Drugs

2**Description**

control: control group will received 16 mg normal saline as placebo intraperitoneally, at the end of procedure

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences, Arash hospital

Full name of responsible person

Dr Asgari

Street address

Rashid street, Resalat highway

City

Tehran

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, Arash hospital

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

Phone

+98 21 7788 8755

Fax

+98 21 7788 8751

Email

asgariza@sina.tums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Zahra Asgari

Position

assistant proffesor

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

Arash Hospital, Rashid street ,Resalat highway

City

Tehran

Postal code**Phone**

+98 21 7788 8755

Fax

+98 21 7788 8751

Email

asgariza@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr sima mozafar Jalali

Position

resident

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

Rashid street, Resalat highway

City

Tehran

Postal code**Phone**

+98 21 7788 8755

Fax

+98 21 7788 8751

Email

simamjalali@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Asgari

Position

assistant proffesor

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

Arash Hospital , Rashid street , Resalat highway

City

Tehran

Postal code**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