Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the analgesia effect of perineal nerve blockage with marcaine with placebo after pelvic floor prolapse surgeries

Protocol summary

Study aim
Determining the relationship between perineal nerve anesthesia and the level of analgesia after pelvic floor prolapse surgeries

Design
Clinical trial with a control group, with parallel groups, randomized single-blind, phase 2 on 25 patients. The rand function of Excel software was used for randomization.

Settings and conduct
In Imam khomeini hospital complex in Tehran, women ward in the intervention group, after the surgery, 2 cc of Marcaine 7.5 mg/ml and in the control group, the same volume of normal saline will be injected inside the vagina 1 cm lateral and behind the ischial spines. The day after the surgery, the visual Analogue scale (VAS) is used to compare the number of analgesics they asked for and the number of nausea feelings. Due to the similarity of the method of intervention and control, the patient's side is blinded. The researcher who performs the analysis at the end is also unaware of the allocation of groups and therefore is blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women aged 30-80 years undergoing various types of pelvic floor prolapse surgeries Exclusion criteria: having concurrent abdominal or laparoscopic surgery

Intervention groups
The intervention includes investigating the effect and side effects of Marcaine as a pudendal nerve block in reducing pain and analgesic use after pelvic floor prolapse surgeries. The control group includes the same people but under the injection of normal saline serum as a placebo with the same volume and in the same region of the pudendal block for comparison.

Main outcome variables
Postoperative pain using VAS scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231025059847N1**
Registration date: **2023-11-09, 1402/08/18**
Registration timing: **prospective**

Last update: **2023-11-09, 1402/08/18**
Update count: **0**

Registration date
2023-11-09, 1402/08/18

Registrant information
Name
Hamideh Nematian
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-11, 1402/08/20

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the analgesia effect of perineal nerve blockage with marcaine with placebo after pelvic floor prolapse surgeries

Public title
Investigating the analgesia effect of pudendal block with placebo after pelvic floor prolapse surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women undergoing pelvic floor prolapse surgery
Exclusion criteria:
History of chronic pelvic pain History of hypersensitivity to blocking drugs, narcotics or analgesics Chronic use of analgesics or narcotics Patients suffering from liver or kidney problems Patients with simultaneous abdominal or laparoscopic surgery
Age
From **30 years** old to **80 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Randomized
Randomization description
This study has two arms. First arm: pudendal block with marcaine. The second arm is the control group with placebo. In this study, random allocation will be done, the type of random allocation is block and the randomization unit is individual. Blocks of 4 will be used for random allocation. The randomization tool is the following online software: https://www.sealedenvelope.com/simple-randomiser/v1/lists Therefore, people will be randomly placed in one of two groups. In this study, due to the fact that the intervention is determined for the surgeon and the patient and is an open-label trial, blinding is not possible, but the analyzers of A and B will be blinded. Concealment will be done in the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding: the researcher who performs the analysis at the end is unaware of the allocation of the groups. So the study is one-side blind. The patient side is not blind.
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, Imam Khomeini hospital complex
Street address
Imam Khomeini Hospital Complex, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733134
Approval date
2023-10-10, 1402/07/18
Ethics committee reference number
IR.TUMS.IKHC.REC.1402.296

Health conditions studied

1

Description of health condition studied
Pelvic floor prolapse surgeries
ICD-10 code
N81.2
ICD-10 code description
Incomplete uterovaginal prolapse

Primary outcomes

1

Description
Pain level after surgery
Timepoint
The day after the surgery
Method of measurement
Visual analogue scale

2

Description
nausea
Timepoint
The day after the surgery
Method of measurement
Asking the patient how often she feels nausea

3

Description
Number of analgesics used
Timepoint
The day after the surgery
Method of measurement
Checking the number of analgesics requests in the file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women undergoing pelvic floor prolapse surgery, 30-80 years old, for whom pudendal block is performed as follows: 2 cc of Marcaine 7.5 mg/ml aspen group of companies inside the vagina, 1 cm lateral and behind the ischial spines.
Category
Treatment - Drugs

2

Description
Control group: Women undergoing pelvic floor prolapse surgery, 30-80 years old, for whom normal saline is administered in the same way as pudendal block after surgery: 2 cc of normal saline 0.9% inside the vagina, 1 cm lateral and behind the ischial spines.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital complex
Full name of responsible person
Hamideh Nematian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Deputy of research and technology center of Tehran University of Medical Sciences
Street address
Tehran university of medical science, Keshavarz Blvd.
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Phone
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Email
tums_edu@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hamide Nematian
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hamide Nematian
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person

Tahereh Eftekhar

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
After unrecognizing the participants, patient's demographic data, study protocol and main outcome information will be shared.

When the data will become available and for how long
The access period starts 3 months after the results are published

To whom data/document is available
All doctors and researchers working in the field of obstetrics and gynecology

Under which criteria data/document could be used
Any data analysis and use of documents in the field of obstetrics and gynecology is allowed

From where data/document is obtainable
The email address of the project manager: Hamide Nematian hnematian6173@gmail.com

What processes are involved for a request to access data/document
Email to the project manager and receive the required data within a month

Comments