Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Compare the effect of intrarectal lidocaine gel and lidocaine gel in combination with fentanyl in pain reduction during in patients undergoing prostate biopsy: a clinical trial

Protocol summary

Summary

Objectives: Compare the intrarectal administration of lidocaine gel with lidocaine gel -fentanyl in pain reduction of prostate biopsy. Study groups: Patients candidate for prostate biopsy. Sample size: 96 patients. Randomization: a table of random number. Blinding: double blind. Control group will be administered 50 gr lidocaine gel 2% and the intervention group will receive 50 µgr intrarectal fentanyl in combination with 50 gr lidocaine gel (2%). Prostate biopsy will be performed after 30 minutes in both groups. Primary outcome: pain intensity based on VAS criteria. Secondary outcomes: Blood pressure, pulse rate and level of consciousness which will be measured and documented by another researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612013773N17**
Registration date: **2017-01-22, 1395/11/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-22, 1395/11/03

Registrant information

Name

Farsad Imani

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of intrarectal lidocaine gel and lidocaine gel in combination with fentanyl in pain reduction during in patients undergoing prostate biopsy: a clinical trial

Public title

A method of pain reduction during prostate biopsy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate for prostate biopsy; Minimum weight 40 kg Exclusion criteria: uncontrolled blood pressure; sensitivity to local anesthetics; advanced heart, renal or hepatic disease; opioid addiction.

Age

From **30 years** old to **80 years** old

Gender

Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not 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
At the begining of Ghods St, Keshavars Blvd
City
Tehran
Postal code
9111174011-140764
Approval date
2016-06-14, 1395/03/25
Ethics committee reference number
IR-TUMS.REC.1395-2678

Health conditions studied

1

Description of health condition studied
Dysplasia of prostate
ICD-10 code
N42.3
ICD-10 code description
Dysplasia of Prostate, Low grade dysplasia

Primary outcomes

1

Description
Pain
Timepoint
Before and During Biopsy
Method of measurement
VAS Score

2

Description
Blood Pressure
Timepoint
Before and During Biopsy
Method of measurement
Monitoring

3

Description
Heart Rate
Timepoint
Before and During Biopsy
Method of measurement
Pulse Oximetry

Secondary outcomes

1

Description
Level of consciousness
Timepoint
Before and during biopsy
Method of measurement
Miller Score

Intervention groups

1

Description
Intervention Group: intrarectal administration of 50 gr lidocaine gel (2%) produced by Sina daro company and 50 mcg fentanyl produced by Rasht-Iran company.
Category
Treatment - Drugs

2

Description
Control Group: intrarectal administration of 50 gr lidocaine gel 2% produsd by Sina daro company.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr. Tayeb Gavili
Street address
Sina Hospital, Hasan Abad Square, Imam Khomeini Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Masoud Yunesian
Street address
6th Floor, Central building of University, Adjacent Ghods St. Boulevard Keshavarz
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tehran University of Medical Sciences
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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Farsad Imani
Position
Anesthesiologist/Associate Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Assistant of Anesthesiology
Other areas of specialty/work
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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