Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of lidocaine gel and methoxyflurane in relieving pain in patients scheduled to undergo elective cystoscopy

Protocol summary

Summary

Purpose: In this study we Compare lidocaine gel and methoxyflurane in relieving pain in patients scheduled to undergo elective cystoscopy. Method: After obtaining informed and written consent and permission, 60 patients between the ages of 20 and 55 years undergoing a cystoscopy procedure enrolled in this interventional non-blind clinical study. Exclusion criteria: Allergy to lidocaine and methoxyflurane, concurrent use of analgesics in recent 24 hours, age>55 years old, addiction, renal failure, neuropathy, liver disease, pregnancy. Patient were randomly allocated to two groups, that one of them received methoxyflurane 5 minutes before cystoscop entrance and another was administered lidocaine 2% gel 15 minutes before procedure then were evaluated and compared heart rate, blood pressure, oxygen saturation and pain (utilizing visual analog scale) before entrance, at the time of drug administration, just at the instrument insertion, during bladder examination, end of procedure and 15 minutes after operation. Method of randomization is computer generated. Whenever during study; if patient had pain with score more than 4 based in visual analog scale, should be administered alfentanyl 10 microgram/kg. We compare dose of administered alfentanyl between two groups. After 2 weeks we will measure alanine transaminase, aspartate transaminase, alkaline phosphatase, creatinine, blood urea nitrogen and urine analysis of the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207253579N3**
Registration date: **2012-12-12, 1391/09/22**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-12-12, 1391/09/22

Registrant information

Name

Alireza Jafari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-12-15, 1391/09/25

Expected recruitment end date

2013-02-08, 1391/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of lidocaine gel and methoxyflurane in relieving pain in patients scheduled to undergo elective cystoscopy

Public title

Comparison of lidocaine gel and methoxyflurane in cystoscopy

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients with American Society of Anesthesiologists Physical Status Classification (ASA class) I and II scheduled to undergo elective cystoscopy and their age is between 20-55 years old. Exclusion criteria: Allergy to lidocaine and methoxyflurane, concurrent use of analgesics in recent 24 hours, age>55 years old, addiction, renal failure, neuropathy, liver disease, pregnancy.
Age
From **20 years** old to **55 years** old
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urology ethic committee of Shahid Beheshti University of Medical Sciences
Street address
Ninth Boostan Ave., Pasdaran St.
City
Tehran
Postal code
Approval date
2012-03-12, 1390/12/22
Ethics committee reference number
16

Health conditions studied

1

Description of health condition studied
Analgesic effect of methoxyflurane and lidocaine gel during cystoscopy
ICD-10 code
y.48.0 y.4
ICD-10 code description
Inhaled anesthetics local anesthetics

Primary outcomes

1

Description
pain
Timepoint
Before entrance, at the time of drug administration, just at the instrument insertion, during bladder examination, end of procedure and 15 minutes after operation
Method of measurement
standard visual analog scale

Secondary outcomes

1

Description
Heart rate
Timepoint
Before entrance, at the time of drug administration, just at the instrument insertion, during bladder examination, end of procedure and 15 minutes after operation
Method of measurement
Electrocardiography monitoring

2

Description
Blood pressure
Timepoint
Before entrance, at the time of drug administration, just at the instrument insertion, during bladder examination, end of procedure and 15 minutes after operation
Method of measurement
Noninvasive blood pressure

3

Description
Blood oxygen saturation
Timepoint
Before entrance, at the time of drug administration, just at the instrument insertion, during bladder examination, end of procedure and 15 minutes after operation
Method of measurement
Pulse Oxymetry

Intervention groups

1

Description
Methoxyflurane is a volatile fluorinated hydrocarbon anesthetic agent that is available with 3 CC ampoules to be used in a penthrox inhaler. The inhaler is primed with

3 CC methoxyflurane. The inhaler dispenses 0.2-0.4% with the dilutor hole open and 0.5-0.7% with it closed. The device contains an oxygen port. We used penthrox inhaler for administration of methoxyflurane with activated charcoal scavenging chamber. We asked the patient to close the dilutor hole with his finger and put the inhaler mouth piece in the mouth and exhale through the mouth piece or the nose. For each patient we used maximum one vial (3cc) without oxygen. No more than two patients are to be administered methoxyflurane per shift. Each inhaler is just for one patient.

Category

Prevention

2

Description

Fifteen minutes before the procedure 20 cc lidocaine gel 2% is administered.

Category

Prevention

3

Description

In each step of the study if pain score is more than 4 (utilizing VAS) we will administer 10 microgram/kg alfentanyl.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafi Nejad Hospital

Full name of responsible person

Alireza Jafari

Street address

Ninth Boostan Ave., Pasdaran St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Goudarzi

Street address

Shahid Chamran Highway,Velenjak St., beside Taleghani Hospital, University of Medical Sciences, third floor

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, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hasti Hassani

Position

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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