

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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 cystoscopy 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 alfentanil 10 microgram/kg. We compare dose of administered alfentanil 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2254 9029

###### Email address

alirezajaffari@sbmu.ac.ir

##### 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 pentrox 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 pentrox 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**

MD/ Resident

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

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Shahid Beheshti University of Medical Sciences

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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*