

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of pre-operative Dexamethasone and Petidine on shivering following general anesthesia in minor urologic surgery

Protocol summary

Summary

(1) Objective: Comparison of pre-operative Dexamethasone and Petidine on shivering following general anesthesia in minor urologic surgeries (2) Design: Interventional, Randomized, Double blind, Without placebo, Unicentral (3) Population and Sampling: 120 patient 25-50 years old (60 in the Dexamethasone group and 60 in the Pethidine group) who were candidate for urologic outpatient surgery (4) Inclusion criteria: Patients with physical status ASA I or II; Undergoing outpatient urologic procedures (Hydrocele, Hernia, Varicoscele); By general anesthesia Exclusion criteria: Patients with history of Hypertension; Diabetes; Gastric ulcer; Massive transfusion; Prolong treatment with corticosteroids (5) Intervention: After premedication with intravenous Midazolam 0.15 milligrams per kilogram and Lidocain 1 milligram per kilogram and Fentanyl 1 microgram per kilogram and before induction of anesthesia; in group D, 8 milligrams intravenous Dexamethasone and in group P, 25 milligrams intravenous Pethidin were injected (6) Main outcome: Post-operative shivering were evaluated using the stated scoring after one hour post-operative.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308284005N8**

Registration date: **2014-11-15, 1393/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-15, 1393/08/24

Registrant information

Name

Khosro Kollahdouzan

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pre-operative Dexamethasone and Petidine on shivering following general anesthesia in minor urologic surgery

Public title

Comparison of pre-operative Dexamethasone and Petidine on shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with physical status ASA I or II; undergoing outpatient urologic procedures (Varicoscele, Hydrocele, Hernia); aged 25-50 years Exclusion criteria:

Patients with history of Hypertension; Diabetes; Gastric ulcer; Massive transfusion; Prolong treatment with corticosteroids

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Tabriz University of Medical Sciences

Street address

Emam Reza Hospital, Golgasht Street, Azadi Avenue

City

Tabriz

Postal code

Approval date

2013-12-18, 1392/09/27

Ethics committee reference number

92156

Health conditions studied

1

Description of health condition studied

Postoperative shivering

ICD-10 code

T88.5

ICD-10 code description

Other complication of anesthesia

Primary outcomes

1

Description

Shivering

Timepoint

Every 10 minute for 1 hour

Method of measurement

Standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

After premedication with intravenous Midazolam 0.15mg/kg and Lidocain 1 mg/kg and Fentanyl 1 µg/kg and before induction of anesthesia, in first group(D), intravenous Dexamethasone 8mg injected and shivering was evaluated after one hour post-operative.

Category

Treatment - Drugs

2

Description

After premedication with intravenous Midazolam 0.15mg/kg and Lidocain 1 mg/kg and Fentanyl 1 µg/kg and before induction of anesthesia, in second group(P), pethidin 8 mg IV injected and shivering was evaluated after one hour post-operative

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Mahmoud Eidy

Street address

Emam Reza Hospital, Golgasht Street, Azadi Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Soleimanpoor

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Research Assistant

City
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

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Person responsible for updating data

Contact

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