Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of ketamine-propofol versus alfentanil-propofol for analgesia and sedation during cystoscopy

Protocol summary

Summary

Objective: Cystoscopy is performed with local anesthesia, regional and general anesthesia to reduce pain and discomfort during this diagnostic method. The aim of this study is to compare the effect of ketamine-propofol with alfentanil-propofol on analgesia and sedation during cystoscopy and comparing the side effects of two drugs and also patient and physician satisfaction. Design: Simple randomization, double blind, without placebo, single center, trial phase 2, including 140 patients candidate for elective cystoscopy. Setting and conduct: Propofol, 1 mg/kg, intravenous. Participants including major eligibility criteria: All patients candidate for cystoscopy. Intervention: Alfentanil, 1 µg/kg, intravenous. Ketamine, 0.5 mg/kg, intravenous. Main outcome measures (variables): Heart rate, systolic blood pressure, diastolic blood pressure, arterial O2 saturation, analgesia score, Ramsay sedation score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201401313289N7**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

Name
Esmail Moshiri
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Arak University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ketamine-propofol versus alfentanil-propofol for analgesia and sedation during cystoscopy

Public title

Ketamine-propofol versus alfentanil-propofol for analgesia during cystoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Elective rigid cystoscopy; either diagnostic or therapeutic; age between 18 and 65. Exclusion Criteria: Patients with allergy to ketamine, propofol, and alfenatnil; pregnancy; emergency cystoscopy; patients on psychiatric medications; alcoholics.

Age

From **18 years** old to **65 years** old

Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this double blind study, the person responsible to assess the items and the patient were not aware of the type of administered drug.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran
City
Arak
Postal code
Approval date
2012-11-28, 1391/09/08
Ethics committee reference number
91-138-10

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R10.3
ICD-10 code description
Pain localized to other parts of lower abdomen

Primary outcomes

1

Description
Heart rate
Timepoint
at time zero and then every 5 minutes
Method of measurement
Cardiac monitoring

2

Description
Systolic blood pressure
Timepoint
at time zero and then every 5 minutes
Method of measurement
Mercury sphygmomanometer

3

Description
Diastolic blood pressure
Timepoint
at time zero and then every 5 minutes
Method of measurement
Mercury sphygmomanometer

4

Description
Arterial O2 saturation
Timepoint
at time zero and then every 5 minutes
Method of measurement
Pulse oximeter

5

Description
Respiratory rate
Timepoint
at time zero and then every 5 minutes
Method of measurement
Cardiac monitoring

6

Description
Analgesia score
Timepoint
Two hours after cystoscopy
Method of measurement
Visual analog scale

7

Description
Sedation score
Timepoint
Two hours after cystoscopy
Method of measurement
Ramsay sedation score

Secondary outcomes

empty

Intervention groups

1

Description
Interventions 1. Alfentanil, 1 µg/kg, intravenous, chemical composition N-{1-[2-(4-ethyl-5-oxo-4,5-dihydro-1H-1,2,3,4-tetrazol-1-yl)ethyl]-4-(methoxymethyl)piperidin-4-yl}-N-phenylpropanamide, trade mark Alfenta, made in Hamelen pharmaceuticals, Germany.
Category
Prevention

2

Description
Interventions 2. Ketamine, 0.5 mg/kg, intravenous, chemical composition RS)-۲-(۲-Chlorophenyl)-۲-(methylamino)cyclohexanone, made in Rotex Medica, Germany.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-asr hospital
Full name of responsible person
Dr Esmaeil Moshiri
Street address
Vali-asr square. Vali-asr hospital. Arak. Iran
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences, Vice Chancellor for Research
Full name of responsible person
Dr Saeed Changizi Ashtiani
Street address
Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran
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Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences, Vice Chancellor for Research
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
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Dr Esmaeil Moshiri
Position
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Person responsible for scientific inquiries

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Name of organization / entity
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Anesthesiologist
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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