

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

dr_moshiri@arakmu.ac.ir

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 alfentanil; 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)- γ -(γ -Chlorophenyl)- γ -(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

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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

City

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

Arak University of Medical Sciences

Full name of responsible person

Dr Esmaeil Moshiri

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Esmaeil Moshiri

Position

Anesthesiologist

Other areas of specialty/work

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Position

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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