Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effects of preoperative Ketamine gargle with Benzidamine on the rate of sore throat after general anesthesia in patients under Hysterectomy during in the year 2011 - 2012 in Tehran Rasul Akram Hospital.

Protocol summary

Summary

Objectives : Comparison the effect of preoperative Ketamine gargle with Benzidamine on the rate of sore throat after general anesthesia Design : Randomized double blind , control with placebo Setting and conduct : Dividing patients into three groups of 20 people and prescribing random Ketamine or Benzydamine or placebo for gargle before induction of anesthesia and intubation Participants including major eligibility criteria; women 15-60 year; ASA = 1- 2 ; patients candidate for elective Hysterectomy Participants excluding major eligibility criteria; The lack of consent of the patients; drug and alcohol abuse; diabetes; HTN ; a history of sore throat and colds causing by infectious during the 2 weeks before surgery; difficult intubation (more than once trying for intubation) Intervention : Prescribing for gargle Ketamine (20 mg in 19 ml normal saline) or Benzydamine (1.5 mg in 19 ml normal saline) or 20 ml of normal saline (placebo), 5 minutes before intubation in three random groups Main outcome measures variables : Check the amount of sore throat in patients in 0 , 2 and 24 hours , after extubation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102311225N1**
Registration date: **2012-12-03, 1391/09/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-03, 1391/09/13

Registrant information

Name

Naghmeh Nikzad

Name of organization / entity

Tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 4436 4895

Email address

n-nikzad@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of preoperative Ketamine gargle with Benzidamine on the rate of sore throat after general anesthesia in patients under Hysterectomy during in the year 2011 - 2012 in Tehran Rasul Akram Hospital.

Public title

Comparison the effect of preoperative Ketamine gargle with Benzidamine on the rate of sore throat after general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria; women 15 to 60 years old ; (ASA = 2, 1) ; candidate for elective Hysterectomy; written consent to the inclusion. Exclusion criteria; no satisfaction ; age under 15 years and above 60 years ; substance abuse Drugs and alcohol ; Diabetes ; HTN ; previous hypersensitivity to anesthetic drugs; liver and kidney failure; Infectious causes of sore throats and colds during the 2 weeks before surgery; difficult intubation (more than once trying for intubation)

Age

From **15 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Tehran university of medical science

Street address

Faculty of medicine , Poorsina avenue , Keshavarz street , Tehran

City

Tehran

Postal code

Approval date

2011-06-27, 1390/04/06

Ethics committee reference number

90/210/3716/ص

Health conditions studied

1

Description of health condition studied

postoperative sorethroat

ICD-10 code

R07

ICD-10 code description

Pain in throat and chest

Primary outcomes

1

Description

postoperative sorethroat

Timepoint

0,2,24 hour postoperation

Method of measurement

VAS

Secondary outcomes

1

Description

heart rate & blood pressure

Timepoint

before & after gargling and intubation

Method of measurement

monitoring of HR & BP

Intervention groups

1

Description

Group Benzydamine ; gargle of 1.5 mg Benzydamine in 20 cc Normal saline five minutes before intubation.

Category

Treatment - Drugs

2

Description

Group Ketamine ; gargle of 20 mg Ketamine in 20 cc Normal saline five minutes before intubation.

Category

Treatment - Drugs

3

Description

Group control ; gargle of 2o cc Normal saline five minutes before intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram hospital

Full name of responsible person
Hamid Reza Feiz MD
Street address
Rasul Akram Hospital , Niayesh avenue, Sattarkhan street, lTehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Tehran university of medical science
Full name of responsible person
Dr Fotoohi
Street address
Faculty of medicine , Poorsina avenue , Keshavarz street , Tehran
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 ,Tehran university of medical science
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
Tehran university of medical sience
Full name of responsible person
Hamid Reza Feiz MD
Position
Assistant Professor of Anesthesiology of Tehran university of medical sience
Other areas of specialty/work
Street address
Rasul Akram Hospital, Niayesh avenue, Sattarkhan Street, Tehran-
City
Tehran
Postal code
Phone
+216 4352326
Fax
Email
hrfaiz@hotmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university of medical science
Full name of responsible person
Hamid Reza Feiz MD
Position
Assistant Professor of Anesthesilogy of Tehran university of medical science
Other areas of specialty/work
Street address
Rasul Akram hospital , Niayesh avenue, Sattarkhan Street , Tehran-
City
Tehran
Postal code
Phone
+98 21 6435 2326
Fax
Email
hrfaiz@hotmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran university of medical science
Full name of responsible person
Hamid Reza Feiz MD
Position
Assistant Professor of Anesthesiology of Tehran university of medical science
Other areas of specialty/work
Street address
Rasul Akram Hospital, Niayesh avenue, Sattarkhan Street, Tehran
City
Tehran
Postal code
Phone
+98 21 6435 2326
Fax
Email
hrfaiz@hotmail.com
Web page address

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