Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of partial saturation of peripheral blood in two intravenous sedation methods (Midazolam+fentanyl) & (midazolam+ketamine) for implant surgery

Protocol summary

Summary

In this double blind prospective clinical trial two groups of patients in total number of 73 who refered for 2-3 implant in mandible to operating room of Isfahan dental school, were studied. In one group combination of midazolam/fentanyl and in second group midazolam/ketamine was prescribed. SPO2 was measured in 6 stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008314224N6**
Registration date: **2011-01-27, 1389/11/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-27, 1389/11/07

Registrant information

Name

Nasser Kaviani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2858

Email address

kaviani@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Isfahan faculty of dentistry

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of partial saturation of peripheral blood in two intravenous sedation methods (Midazolam+fentanyl) & (midazolam+ketamine) for implant surgery

Public title

Comparative evaluation of partial saturation of peripheral blood in two intravenous sedation methods (Midazolam+fentanyl) & (midazolam+ketamine) for implant surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-beind older than 18 2- patient do not use drugs 3-patients do not have heart respiratory or CNS disease 4-satisfaction to be case of study. Exclusion criteria 1-Need to more than 90 min for surgery 2-surgical complication 3-need to inject more than 4.8 ml lidocain for local anesthesia

Age

From **18 years** old to **88 years** old

Gender

Both

Phase

2

Groups that have been masked
No information
Sample size
Target sample size: **73**
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
Vice chancellor for research of Isfahan faculty of dentistry
Street address
Shohadaye sofe street
City
Isfahan
Postal code
Approval date
2009-07-13, 1388/04/22
Ethics committee reference number
388187

Health conditions studied

1

Description of health condition studied
Partial Saturation of peripheral blood
ICD-10 code
T78.8
ICD-10 code description
Other adverse effects, not elsewhere classified

Primary outcomes

1

Description
Partial Saturation of peripheral blood
Timepoint
before and 5 & 10 & 20 & 40 minutes after drug injection
Method of measurement
observation and examination

Secondary outcomes

1

Description
Hypoxia & sometimes sizure
Timepoint
Continuous
Method of measurement
Observation & Examination

Intervention groups

1

Description
In one group combination of midazolam/fentanyl(1mg midazolam & 25micro gram fentanyl so 1mg midazolam every 2 minutes until being conscious sedated) so 1mg midazolam every 2 minutes until being conscious sedated).
Category
Treatment - Drugs

2

Description
In second group midazolam/ketamine was prescribed(1mg midazolam & 20mg ketamine so 1mg midazolam every 2 minutes until being conscious sedated).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan faculty of dentistry
Full name of responsible person
Dr Naser Kaviani
Street address
Shohadaye sofe street
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Isfahan faculty of dentistry
Full name of responsible person
Aminallah Tavangar
Street address
Shohadaye sofe street
City

Isfahan

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 of Isfahan faculty of dentistry

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of dentistry

Full name of responsible person

Dr Naser Kaviani

Position

Anesthesiologist

Other areas of specialty/work

Street address

Faculty of dentistry, Shohadaye sofe street

City

Isfahan

Postal code

Phone

+98 31 1792 2858

Fax

Email

kaviani@dnt.mui.ac.ir , kavianidoctor@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of dentistry

Full name of responsible person

Mehdi Aminzadeh

Position

Dentistry student

Other areas of specialty/work

Street address

Dental school, Shohadaye sofe street

City

Isfahan

Postal code

Phone

Fax

Email

aminzadehmehdi@yahoo.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