

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

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

Protocol summary

dentistry

Summary

In this double blind prospective clinical trial two groups of patients in total number of 73 who referred 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.

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

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

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 sature

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

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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

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Phone

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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