

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Compressive evaluation of change of blood glucose during sedation with Midazolam and Propofol in implant surgery

Protocol summary

Summary

Objectives: Sudden changes in blood glucose level is mainly due to patient stress, operation related stresses and injection of anesthetics containing epinephrine, which can cause problems for both patient and dentist. Therefore, it is recommended to constantly monitor the blood glucose level and maintain it in its normal range.

Design: This study is prospective randomized clinical trial.

Setting and conduct: 33 healthy patients undergoing dental implant surgery select and divide into two groups. Conscious sedation in one group perform by midazolam and in the other group carry out by propofol. Pre-operation stress and blood glucose level measure in 4 different stages including: 1) Before operation, 2) Two minutes after local anesthetic injection, 3) 10 minutes after onset of operation and 4) At the end of operation and then result analyzed. Participants including major eligibility criteria: all of people in study must have ASA I,II; Age between 35-60 years; No diabetes disease; Not intake Corton; Need 2 or 3 implant; No contraindication of use of Midazolam and Propofol and if they have Need to bone or sinus surgery; Systemic disease; Problem during surgery; time of surgery over than 1.5 hours omitted from study. Intervention: in this study uses of 2 intro-venous sedative drugs, Midazolam in one groups of patients and propofol in another groups. main outcome measures (variables): patient's blood glucose measure in 4 different times during surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303144224N20**

Registration date: **2013-07-24, 1392/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-24, 1392/05/02

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 dental school, Dentistry school, Isfahan university of medical science, Hezar Jarib street, Isfahan, Iran.

Expected recruitment start date

2013-04-06, 1392/01/17

Expected recruitment end date

2013-07-26, 1392/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compressive evaluation of change of blood glucose during sedation with Midazolam and Propofol in implant surgery

Public title

Compressive of blood glucose between 2 sedative drugs Midazolam and Propofol in implant surgery

Purpose

Health service research

Inclusion/Exclusion criteria
 Inclusion Criteria: ASA I,II: Age between 35-60 years: No diabetes disease: Not intake Corton: Having satisfaction about sedation and blood glucose measurement: Need 2 or 3 implant: No contraindication of use of Midazolam and Propofol. Exclusion Criteria: No patient satisfaction: Need to bone or sinus surgery: Systemic disease: Problem during surgery: Time of surgery over than 90 minutes.

Age
 From **35 years** old to **60 years** old

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **32**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not 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 university of medical sciences

Street address
 Dental school, University of medical sciences, Hezar Jerib st, Isfahan

City
 Isfahan

Postal code

Approval date
 2012-09-24, 1391/07/03

Ethics committee reference number
 388428

Health conditions studied

1

Description of health condition studied
 Blood glucose

ICD-10 code

R73

ICD-10 code description

Elevated blood glucose level

Primary outcomes

1

Description
 blood glucose

Timepoint
 in 4 different times during surgery

Method of measurement
 Acuu chek system

Secondary outcomes

1

Description
 Anxiety

Timepoint
 one time before surgery

Method of measurement
 according to DAS scale

Intervention groups

1

Description
 Admistartion1 drug regime to 1 patients groups: One milligram midazolam (Tehran Chemie Pharmaceutical co, Iran) inject and when needed, it repeat every 2 minutes until the patient entered the sedated condition.

Category
 Treatment - Drugs

2

Description
 Admistartion1 drug regime to 1 patients groups: 25µg/kg/min propofol (Dongkook pharma Co, Korea) by infusion pomp.

Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
 Dental school of Isfahan university of medical sciences

Full name of responsible person
 dr. Mina Shahtoosi

Street address
 Surgery center, Dentistry school, Isfahan university of medical science, Hezar Jarib street, Isfahan, Iran.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for Research of Isfahan university of medical sciences

Full name of responsible person

Mr Tavangar

Street address

Dentistry school, Hezar Jarib street, Isfahan

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 university of medical sciences

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

Dental school of Isfahan medical sciences

Full name of responsible person

Mina Shahtoosi

Position

Dental resident

Other areas of specialty/work

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inquiries

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Full name of responsible person

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Position

Anesthesiologist, Assistant professor

Other areas of specialty/work

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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