Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of preoperative clonazepam to reduce anxiety of patients referred to the Department of Surgery, Shiraz Dental School

Protocol summary

Summary
The aim of this study is to determine the effect of clonazepam to reduce anxiety before surgery in patients referred to the Department of Surgery, Shiraz Dental School. Among under 18 years old patients referred to this center, 30 patients will receive placebo and 30 patients will receive drug, that is a single dose of clonazepam 2 M.G an hour before surgery. Anxiety is shown by these indices: Visual Analogue Scale, blood pressure, pulse rate and oxygen saturation of blood.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201012195420N1**
Registration date: **2011-06-18, 1390/03/28**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2011-06-18, 1390/03/28

Registrant information
Name
Navid Arasteh
Name of organization / entity
Shiraz Dental School
Country
Iran (Islamic Republic of)
Phone
+98 71 1230 1192
Email address
arastehn@sums.ac.ir

Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences and Health Services

Expected recruitment start date
2010-12-22, 1389/10/01
Expected recruitment end date
2011-04-21, 1390/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of preoperative clonazepam to reduce anxiety of patients referred to the Department of Surgery, Shiraz Dental School

Public title
The effect of clonazepam to reduce anxiety
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria: patients referred to the Department of Surgery, Shiraz Dental School. Exclusion Criteria: children and people under 18; addicts; smoking; all systemic diseases; women during menstruation; and all drugs consumers.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
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)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences and Health Services
Street address
Zand st.
City
Shiraz
Postal code
Approval date
2011-05-22, 1390/03/01
Ethics committee reference number
CT-90-5558

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F40
ICD-10 code description
Phobic anxiety disorders

Primary outcomes

1

Description
Anxiety
Timepoint
1 hour
Method of measurement
Visual Analogue Scale

2

Description
Blood pressure
Timepoint
1 hour
Method of measurement
mm HG by using a Digital Manometer

3

Description
Pulse rate
Timepoint
1 hour
Method of measurement
number per minutes by Digital Pulse Oximetry

4

Description
Oxygen saturation of blood
Timepoint
1 hour
Method of measurement
percent by Digital Pulse Oximetry

Secondary outcomes

empty

Intervention groups

1

Description
One dose of clonazepam 2 m.g one hour before surgery
Category
Treatment - Drugs

2

Description
Placebo one hour before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Dental School
Full name of responsible person
Navid Arasteh
Street address
Ghasro dasht st.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences and Health Services
Full name of responsible person
Dr. Gholam Reza Hatam

Street address
Zand st.
City
Shiraz
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 Shiraz University of Medical Sciences and Health Services
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
Shiraz Dental School
Full name of responsible person
Navid Arasteh
Position
student
Other areas of specialty/work
Street address
Ghasro dasht st.
City
Shiraz
Postal code
Phone
+98 71 1626 2193
Fax
Email
arastehn@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz Dental School
Full name of responsible person
Dr. Barbod Zamiri
Position
Oromaxilo Facial Surgeon
Other areas of specialty/work
Street address
Ghasro dasht st.
City
Shiraz
Postal code
Phone
+98 71 1626 2193
Fax
Email
zamirib@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz Dental School
Full name of responsible person
Navid Arasteh
Position
student
Other areas of specialty/work
Street address
Ghasro dasht st.
City
Shiraz
Postal code
Phone
+98 71 1230 1192
Fax
Email
arastehn@sums.ac.ir
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