

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Randomized placebo controlled clinical trial of the effect of hydroxyzine on bruxism in children and adolescents

Protocol summary

Summary

This is a randomized placebo controlled clinical trial investigating the effect of hydroxyzine (25 - 50 mg/day) on 30 children and adolescents with bruxism. There are two parallel groups. One group will receive hydroxyzine and the other group will receive placebo. Assessments will be occurred before the intervention and one month after the onset of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110203930N13**

Registration date: **2012-07-23, 1391/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-23, 1391/05/02

Registrant information

Name

Ahmad Ghanizadeh

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 3070

Email address

ghanizad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-10-25, 1390/08/03

Expected recruitment end date

2012-06-23, 1391/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized placebo controlled clinical trial of the effect of hydroxyzine on bruxism in children and adolescents

Public title

The effect of hydroxyzine on bruxism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children with age range of 3 to 17 years from both gender with bruxism. Exclusion criteria: Concurrent behavior therapy, psychoanalysis, or relaxation therapy for bruxism; taking benzodiazepines.

Age

From **3 years** old to **17 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

Shiraz University of Medical Sciences

Street address

Chamran street- Hafez hospital

City

Shiraz

Postal code**Approval date**

2011-10-24, 1390/08/02

Ethics committee reference number

CT- 90-2796

Health conditions studied**1****Description of health condition studied**

Bruxism

ICD-10 code

F45.8

ICD-10 code description

Other somatoform disorders

Primary outcomes**1****Description**

Visual Analogue scale

Timepoint

Pre and post intervention

Method of measurement

Parent report

Secondary outcomes

empty

Intervention groups**1****Description**

Hydroxizine, 25 - 50 mg/day

Category

Treatment - Drugs

2**Description**

Placebo

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Research Center for Psychiatry and Behavioral Sciences

Full name of responsible person

Samanah Zare

Street address

Hafez hospital, Chamran Street

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Gholam Reza Hatam

Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

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, Shiraz 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**

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical sciences

Full name of responsible person

Ahmad Ghanizadeh

Position

MD

Other areas of specialty/work**Street address**

Hafez Hospital, Chamran street

City

Shiraz

Postal code**Phone**

+98 71 1627 3070

Fax**Email**

ghanizad@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

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