

# 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*