

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Efficacy of Oral Diazepam in Decrease Frequency, Severity and Duration of Bruxism in Children With Bruxism in Isfahan in 2014/2015

Protocol summary

Summary

Objectives: Efficacy of oral diazepam in Frequency, severity and duration reduction due to bruxism in children, Isfahan, 2014/2015. Design: Bruxism is a common childhood problem worldwide. There is no effective therapy of the disorder in the literature. So we decide to evaluate the efficacy of the drug in 90 otherwise healthy children in age of 2-15 years in a triple blind clinical trial. Setting and conduct: Enrolled children are divided to three groups as low dose diazepam, high dose diazepam and placebo. The drugs are blindly packed in different colors for age groups of 2-8 and 8-15 year. For age group of 2-8 years 2.5 mg Diazepam (code A- half a 5 mg pill) is considered as low dose, 5 mg Diazepam (code B- half a 10 mg pill) as high dose, and half an identical placebo pill (code C-) as a placebo drug. For age group of 8-15 years 5 mg Diazepam (code A- 5 mg pill) is considered as low dose, 10 mg Diazepam (code B- 10 mg pill) as high dose, and an identical placebo pill (code C-) as a placebo drug. The researcher will assess inclusion criteria and include the children in the study. Each participant will receive 10 drug and advise to consume before bed for 5 nights and then as alternate night for 10 days. After that, we will follow up patients during 2 weeks, 1 months and 3 months in order to check symptoms severity, possible adverse effects and consumption/avoiding the consumption of the drug. Data will be analyzed by SPSS Inclusion criteria including: Bruxism reported by parents; No previous seizure disorder or abnormal movement during sleep; Age 2-15 years; Not taking any medications that affects the neuromuscular system, such as anticonvulsants, benzodiazepines, muscle relaxant and antidepressants; Visual Analogue Score (VAS) will be calculated for included patients by the score of duration, intensity and frequency of bruxism episodes. Exclusion criteria including: Inability to take a pill; Drug hypersensitivity. Interventions: For age group of 2-8 years 2.5 mg Diazepam (code A- half a 5 mg pill) is considered as low

dose, 5 mg Diazepam (code B- half a 10 mg pill) as high dose, and half an identical placebo pill (code C-) as a placebo drug. For age group of 8-15 years 5 mg Diazepam (code A- 5 mg pill) is considered as low dose, 10 mg Diazepam (code B- 10 mg pill) as high dose, and an identical placebo pill (code C-) as a placebo drug. Each participant will receive 10 drug and advise to consume before bed for 5 nights and then as alternate night for 10 days. Main outcome measures: Intensity, Frequency.

General information

Acronym

Efficacy of diazepam in childhood bruxism

IRCT registration information

IRCT registration number: **IRCT2016031225780N2**

Registration date: **2016-08-21, 1395/05/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-21, 1395/05/31

Registrant information

Name

Naser Mostafavy

Name of organization / entity

Department of Pediatrics, School of Medical, Isfahan University of Medical Sciences, Hezar Jerib

Country

Iran (Islamic Republic of)

Phone

none

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n_mostafavy@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of
Medical Sciences, Hezar Jerib Street, Isfahan, I.R.Iran

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-03-17, 1394/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Oral Diazepam in Decrease
Frequency, Severity and Duration of Bruxism in Children
With Bruxism in Isfahan in 2014/2015

Public title

Efficacy of Oral Diazepam in Decrease
Frequency, Severity and Duration of Bruxism in Children
With Bruxism in Isfahan in 2014/2015

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria including: Bruxism reported by parents;
No previous seizure disorder or abnormal movement
during sleep; Age 2-15 years; Not taking any medications
that affects the neuromuscular system, such as
anticonvulsants, benzodiazepines, muscle relaxant and
antidepressants; Visual Analogue Score (VAS) will be
calculated for included patients by the score of duration,
intensity and frequency of bruxism episodes. Exclusion
criteria including: Inability to take a pill; Drug
hypersensitivity.

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1**Ethics committee****Name of ethics committee**

Ethics Committee, Isfahan University of Medical
Sciences

Street address

Ethics Committee, Isfahan University of Medical
Sciences, Hezar Jerib Street, Isfahan, I.R.Iran

City

Isfahan

Postal code

8174673461

Approval date

2015-05-27, 1394/03/06

Ethics committee reference number

ir.mui.rec.1394.3.307

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**

Bruxism

Timepoint

2 Weeks, 1 Month, 3 Month after administration

Method of measurement

Questionnaire

Secondary outcomes

1**Description**

Intensity, Frequency

Timepoint

2 Week, 2 Month, 6 Month

Method of measurement

Questionnaire

Intervention groups

1**Description**

To subgroups 3 from both age group, placebo was gave
as followa; 2-8-year-old: half a placebo tablet 8-12-year-
old: a placebo tablet Other study process is similar for

placebo and diazepam.

Category

Treatment - Drugs

2

Description

For age group of 2-8 years 2.5 mg Diazepam(code A- half a 5 mg pill) is considered as low dose and 5 mg Diazepam(code B- half a 10 mg pill) as high dose. For age group of 8-15 years 5 mg Diazepam(code A- 5 mg pill) is considered as low dose and 10 mg Diazepam(code B- 10 mg pill) as high dose.Each participant will receive 10 drug and advise to consume before bed for 5 nights and then as alternate night for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

EmamHossein Hospital, Emamkhomeini street, Isfahan, Iran

Full name of responsible person

Dr Sayed Nasser – Mostafavy, Dr Majid Khademian

Street address

EmamHossein Hospital, Emamkhomeini street, Isfahan, Iran

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Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

ice Chancellor for Research, Isfahan University of Medical Sciences, Maryam V akili

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan, I.R.Iran

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Isfahan

Grant name

394

Grant code / Reference number

307

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, 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

Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan,

Full name of responsible person

Dr Sayed Nasser – Mostafavy, Dr Majid Khademian

Position

Assistance Professor in Pediatrics Department

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Sayed Nasser – Mostafavy, Dr Majid Khademian

Position

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Person responsible for updating data

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Position

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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