Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy Comparison of Three Approaches of Pharmacotherapy, Appliance Therapy and Psychotherapy on Sleep Bruxism Reduction of 6 to 12-year-old children

Protocol summary

Study aim

Efficacy Determination of three therapeutic approaches in schoolchildren with sleep bruxism

Design

three arm parallel group randomized trial with blinded outcome assessment and data analysis

Settings and conduct

This study is being performed on 33 children aged 6 to 12 years old who have been referred to the Department of Pediatrics, Qazvin Faculty of Dentistry with complaint of sleep bruxism or have been identified during school examination. After providing explanations and obtaining consent, oral photography is prepared and oral symptoms of bruxism are examined. Pediatricians examine the patient in terms of parasitic infections, nutritional deficiencies, asthma and allergies, hormonal problems and blood disorders, and perform the necessary tests including CBC diff, Thyroid Function Test and Stool Exam. Prior to performing polysomnography, all dental infections are treated by a pediatric dentist. The frequency and intensity of sleep bruxism are recorded according to the parents report and the anxiety questionnaire is also obtained from the patient. Samples are randomly assigned to one of three treatment groups. The first group enters the psychotherapy course with a child psychologist for 3 months and the second group receives oral Lorazepam 5 mg/kg before bedtime (max dose of 2 mg) for 1 month. To the third group after impression taking, the hard night guard will be delivered for a period of three months. During the treatment, a telephone number will be provided to patients for answering questions and possible problems. At the end of the treatment, the outcome evaluator (blinded about the type of intervention) examining the intensity, frequency and extent of the parents' satisfaction with the treatment. The statistician is blind to the type of intervention and performs statistical analysis using ANOVA.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Complaint of tooth attrition or bruxism, 2) one of the following: dental facets- bruxism sounds for at least 3 nights in a week, jaw muscle soreness, 3) Both of these according to PSG: muscle activity during sleep, absence of comorbid seizure movements exclusion criteria: 1) severe malocclusions, 2) predisposing disease or conditions, 3) triggering dental condition or infections, 4) use of medicines with effect on sleep conditions (selective serotonin reuptake inhibitors, psychotropic, anti-depression, anti-anxiety, anticonvulsion, analgesic), 5) severe anxiety according to anxiety questionnaire

Intervention groups

1- pharmacotherapy: Administration of Lorazepam 0.5 mg / kg body weight, at night before bedtime, for 1 month 2- appliance therapy: Hard night guard use for 3 months 3-psychotherapy: 10 sessions (3 months) of psychological therapy and relaxation training using the Benson model

Main outcome variables

Change in frequency and intensity of sleep bruxism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180104038218N1**
Registration date: **2018-04-02, 1397/01/13**
Registration timing: **retrospective**

Last update: **2018-04-02, 1397/01/13**
Update count: **0**

Registration date

2018-04-02, 1397/01/13

Registrant information

Name
Razieh Jabbarian
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-04, 1396/11/15
Expected recruitment end date
2018-03-06, 1396/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy Comparison of Three Approaches of Pharmacotherapy, Appliance Therapy and Psychotherapy on Sleep Bruxism Reduction of 6 to 12-year-old children

Public title
Comparison of Three Different Therapeutic Approaches in School-Aged children with Sleep Bruxism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Complaint of tooth attrition or bruxism one of the following: dental facets- bruxism sounds for at least 3 nights in a week, jaw muscle soreness Both of these according to PSG: muscle activity during sleep, absence of comorbid seizure movements
Exclusion criteria:
severe malocclusions predisposing disease or conditions triggering dental condition or infections use of medicines with effect on sleep conditions (selective serotonin reuptake inhibitors, psychotropic, anti-depression, anti-anxiety, anticonvulsion, analgesic) severe anxiety according to anxiety questionnaire
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **33**
Randomization (investigator's opinion)
Randomized
Randomization description
By simple lottery, the order of filling the intervention groups was determined and numbers of 1 to 3 assigned to each of the interventions. Each of the samples was assigned a number from 1 to 33. By random selection of the starting point in the table of random numbers, the movement in the horizontal or vertical path continued, the first number smaller than 33 as the first sample entered group one, followed by the other numbers less than 33. After capacity completion of the first group, groups two and three were completed in the same way.
Blinding (investigator's opinion)
Double blinded
Blinding description
Outcome evaluation will be implemented by an intervention-blind operator other than researcher and care taker, using randomized numbers for each sample. Results are delivered to statistician by numbers.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Qazvin University of Medical Sciences
Street address
Bahonar Boulvard
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2017-09-18, 1396/06/27
Ethics committee reference number
IR.QUMS.REC.1396.248

Health conditions studied

1

Description of health condition studied
sleep bruxism
ICD-10 code
G47.63
ICD-10 code description
Sleep related bruxism

Primary outcomes

1

Description
frequency of sleep bruxism
Timepoint
At the beginning of the study and after 3 months in the intervention of the psychotherapy and appliance therapy and 1 month later in the pharmacotherapy group
Method of measurement
Clinical Question According to the parents report (frequency of sleep bruxism), Visual Analogue Scale according to Parents report (intensity of sleep bruxism)

2

Description
Intensity of sleep bruxism
Timepoint
At the beginning of the study and after 3 months in the intervention of the psychotherapy and appliance therapy and 1 month later in the pharmacotherapy group
Method of measurement
Clinical Question According to the parents report (frequency of sleep bruxism), Visual Analogue Scale according to Parents report (intensity of sleep bruxism)

Secondary outcomes

1

Description
anxiety score
Timepoint
at the begining and end of each intervention
Method of measurement
anxiety questionnaire

Intervention groups

1

Description
Intervention group: 10 sessions (3 months) of psychological therapy and relaxation training using the Benson model
Category
Treatment - Other

2

Description
Intervention group: appliance therapy with hard night guard for 3 months
Category
Treatment - Devices

3

Description
Intervention group: Pharmacotherapy with oral Lorazepam 0.05 mg / kg for 1 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin university of medical sciences, Dentistry faculty
Full name of responsible person
Razieh Jabbarian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Razieh Jabbarian

Position

postgraduate student of pediatric dentistry

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable