

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

efficacy and safety of premedication with single dose of oral" pregabalin" in children with dental anxiety

Protocol summary

Summary

(1) Objectives: The aim of the study is to evaluate the anxiolytic efficacy of oral pregabalin in children with dental anxiety. If it is effective, it would be introduced to pediatric dentists as an option with less side effects and more safety in conscious sedation procedures. (2) Design: Eligible subjects will be screened 4-8 weeks prior to scheduled dental appointment and informed consent will be obtained from parents or legal guardians. Two similar dental appointments will be scheduled for each subject; the only difference will be the premedication agent that will be the placebo for the first visit and the single dose of oral pregabalin for the second visit. According to AAPD guidelines and also the previous study on the onset of action of single dose of oral pregabalin, we will urge parents to keep their child NPO for at least 6 hours prior to procedure and to be at office 1.5 hours before the dental procedure (3) Setting and conduct: In this study two different scales will be used for measuring anxiety: 1) Visual Analogue Scale for Anxiety (VAS-A), 2) the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS). Visual Analogue Scale for Sedation will be used for measuring the sedation. One hour post dose, the sedation level and the anxiety will be reassessed and if it is possible regarding the child's cooperation (According to Frankle's behavior scale, grade 3 and 4 will be regarded as treatable and cooperate in this study), the dental procedure will be started with injection. The patient's behavior will also be assessed during the treatment procedure based on Frankle's behavior scale. During the whole procedure -from the premedication to discharge- the patient's vital signs will be monitored and will be recorded by an anesthesiologist and the emergency box, respiratory resuscitation devices and oxygen delivery system will be provided near the dental chair. (4) Participants including major eligibility criteria: a) Age: 5-7, b) Mentally and physically healthy (ASAI), c) Informed consent from the parents or legally guardians, d) CFSS-DS score should be

38 or more at the screening visit, e) each patient should have at least 2 posterior primary teeth which need pulpotomy treatment. (5) Intervention: At the first scheduled dental appointment all patients will receive 'placebo' 1 hour prior to the treatment and at the second appointment they will receive 'pregabalin' (Cap 75 mg) 1 hour before the treatment. (6) main outcome measures: The patient's anxiety, the level of sedation will be assessed and recorded before and after the administration of drug. The child's behavior during the treatment will be assessed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206131674N2**
Registration date: **2012-07-02, 1391/04/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-02, 1391/04/12

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz

University Of Medical Sciences

Expected recruitment start date

2012-06-14, 1391/03/25

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy and safety of premedication with single dose of oral " pregabalin" in children with dental anxiety

Public title

effect of oral-pregabalin in children with dental anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

a) Age: 5-7, b) Mentally and physically healthy (ASAI), c) Informed consent from the parents or legally guardians, d) CFSS-DS score should be 38 or more at the screening visit, e) each patient should have at least 2 posterior primary teeth which need pulpotomy treatment. Patients will be excluded from the study if any of the above mentioned criteria being lost.

Age

From **5 years** old to **7 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Of Shiraz University Of Medical

Sciences

Street address

Zand Street . Next to Red Crescent Organization .
headquarters of Shiraz University of Medical Sciences
. Seventh Floor .Vice chancellor for research, Shiraz
University of Medical Sciences

City

Shiraz

Postal code

1978-71345

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CT91-4585

Health conditions studied

1

Description of health condition studied

children with dental anxiety

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of childhood

Primary outcomes

1

Description

Visual Analogue Scale for Anxiety

Timepoint

Initial examination session, 5 minutes before taking the drug, an hour after taking the medicine and before discharge

Method of measurement

100 mm during the two leftmost and right, respectively, which indicates are "no anxiety" and "extremely anxious"

2

Description

Visual Analogue Scale for Sedation

Timepoint

Initial examination session, 5 minutes before taking the drug, an hour after taking the medicine and before discharge

Method of measurement

Line is 100 mm and the patient's sedation from left to right, respectively, of "not quiet at all" to "extremely slow by" grading does

3

Description

Ramsay scale

Timepoint

Initial examination session, 5 minutes before taking the drug, an hour after taking the medicine and before discharge

Method of measurement

Sedation can be divided into 6 levels

Secondary outcomes

1

Description

Nausea. Dizziness and drowsiness. Skin allergy. Blurred vision

Timepoint

During and after procedure

Method of measurement

Direct observation by the physician and patient reports

Intervention groups

1

Description

Patients are divided into two categories: The first meeting of "placebo" one hour before treatment is given to the patient. The patient's parents before feeding to the child's medication and one hour after the information needed to assess the effect of the drug are collected.

Category

Treatment - Drugs

2

Description

At the second meeting "oral Pregabalin" up to 75 mg one hour before treatment is given to the patient. The patient's parents before feeding to the child's medication and one hour after the information needed to assess the effect of the drug are collected

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School Of Shiraz University Of Medical Sciences

Full name of responsible person

Tahereh Eskandarian

Street address

Pediatric Dentistry

City

Fars

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Gholamreza Hatam

Street address

Vice-Chancellery of Research and Technology

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Tahereh Eskandarian

Position

Assistant Professor, Department of Pediatric Dentistry

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work

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Full name of responsible person

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Position

Resident, Department of Pediatric Dentistry

Other areas of specialty/work

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Dental School Of Shiraz University Of Medical Sciences

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