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

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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
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Fars

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University Of Medical Sciences
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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
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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