Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of hypnosis,nitrous oxide and conventional behavior guidance on anxiety level of school-age children during local anesthesia injection and dental extraction

Protocol summary

Study aim

Determination the effect of hypnosis,nitrous oxide and conventional behavior guidance on anxiety level of school-age children during local anesthesia injection and dental extraction

Design

Three arm parallel group randomized trial

Settings and conduct

Among children referred to pediatric dentistry department of dental faculty and need tooth extraction ,75 children will be recruited in the study.Children who have mild to moderate anxiety randomly will be assigned into three groups:1- hypnotism 2-nitrous oxide 3-conventional behavior guidance.In treatment phase for all children,10 minutes after local anesthesia administration,the tooth will be extracted.Child anxiety will be recorded before and during the local anesthesia and during the dental extraction .For this reason, child's vital signs such as oxygen saturation and heart rate will be recorded by pulseoximeter. During all treatment procedures a camera will record the child behavior and his anxiety level will be scored by examiner.At the end of the treatment the child anxiety level will also be evaluated by Venham picture test.Finally the children anxiety level will be compared between groups.

Participants/Inclusion and exclusion criteria

7-11 year-old school-aged children Having mild to moderate anxiety Having no chronic systemic diseases Having no mental retardation and autism Having no history of dental treatment with hypnosis or nitrous oxide Having primary molar candidate for extraction

Intervention groups

Hypnotism group Nitrous oxide group Conventional behavior guidance group

Main outcome variables

Anxiety level ;Heart rate ;Oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161007030193N3**
Registration date: **2019-01-28, 1397/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-28, 1397/11/08**
Update count: **0**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

Iman Parisay

Name of organization / entity

Mashhad University of Medical Sciences-Mashhad Dental Faculty

Country

Iran (Islamic Republic of)

Phone

+98 51 3608 6977

Email address

parisayi@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effect of hypnosis,nitrous oxide and conventional behavior guidance on anxiety level of school-age children during local anesthesia injection and dental extraction

Public title
Comparison the effect of hypnosis,nitrous oxide and conventional behavior guidance on anxiety level of school-age children during local anesthesia injection and dental extraction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
7-11 year-old school-aged children Having mild to moderate anxiety Having no chronic systemic diseases Having no mental retardation and autism Having no history of dental treatment with hypnosis or nitrous oxide Having primary molar candidate for extraction
Exclusion criteria:
Uncooperative patient Not hypnosis

Age
From **7 years** old to **11 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study the participants divided into three groups by block randomization method by use of web program "randomizer.org"

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Mashhad Dental Faculty, Vakil Abbad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
91735

Approval date
2018-06-13, 1397/03/23

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1397.026

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F93.1

ICD-10 code description
Phobic anxiety disorder of childhood

Primary outcomes

1

Description
Anxiety level

Timepoint
before local anesthesia injection-during local anesthesia injection- during dental extraction

Method of measurement
Venham Clinical Anxiety and Cooperation Scale

Secondary outcomes

1

Description
Heart rate

Timepoint
Before local anesthesia injection, during local anesthesia injection, during dental extraction

Method of measurement
Pulsoximetre

2

Description
Oxygen saturation

Timepoint
Before local anesthesia injection, during local anesthesia injection, during dental extraction

Method of measurement
Pulsoximetre

Intervention groups

1

Description

Intervention group 1: participants who were hypnotized during local anesthesia injection and dental extraction.The hypnosis intervention included a standard 3-minute progressive muscle relaxation induction followed by a 5-minute deepening procedure aimed at increasing the patients' focus, absorption, and concentration. In the intervention phase the hypnotic suggestions were aimed at modifying their perception of pain.

Category

Treatment - Other

2

Description

Intervention group 2: participants who were sedated by nitrous oxide during local anesthesia injection and dental extraction. At first introduction of 100 percent oxygen for two minutes followed by titration of nitrous oxide in 10 percent intervals up to 40% concentration of nitous oxide to achieve ideal sedation.After local anesthesia injection and dental extraction. the nitrous oxide flow is terminated, 100 percent oxygen should be delivered for five minutes

Category

Treatment - Drugs

3

Description

Control group: participants who were managed during local anesthesia injection and dental extraction by conventional behavior guidance such as Tell Show Do technique and roll modeling and voice control method

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental Faculty

Full name of responsible person

Dr.Iman Parisay

Street address

Mashhad Dental Faculty-Vakil Abbad BLVD

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Email

parisayi@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Research Vice chancellor of Mashhad University of Medical Sciences -Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Iman Parisay

Position

Associate Professor of pediatric dentistry department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Mashhad Dental Faculty-Vakil Abbad BLVD

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone
+98 51 3882 9501
Fax
Email
parisayi@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Iman Parisay
Position
Associate Professor of pediatric dentistry department
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Mashhad Dental Faculty-Vakil Abbad BLVD
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9501
Fax
Email
parisayi@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Iman Parisay
Position
Associate Professor of pediatric dentistry department
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Mashhad Dental Faculty-Vakil Abbad BLVD
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9501
Fax
Email
parisayi@mums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data are available among corresponding author
When the data will become available and for how long
After publication of the article
To whom data/document is available
Every one who needs for scientific aims such as researchers who work on systematic review projects
Under which criteria data/document could be used
For research aims by formal request
From where data/document is obtainable
Contact with corresponding author by e-mail address
What processes are involved for a request to access data/document
After discussion the authors decide to accept or reject the request
Comments