

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Efficacy of behavior management techniques to prevent unnecessary anesthesia in uncooperative children referred to dental hospital of Tabriz University, 2012

Protocol summary

Summary

Background and aims: Despite risks and side effects of general anesthesia (GA), a considerable number of referrals are made due to lack of cooperation in children for dental treatments. The present study aimed at evaluating the efficacy of behavior management techniques to prevent unnecessary GA in uncooperative children referred to a dental hospital. Materials and methods: The study included a total sample of eighty 3-6 year-old uncooperative children referred by general (29 cases) and pediatric dentists (51 cases) to a dental hospital for treatment under GA. Subjects were randomly divided into experimental (E, n = 40) and control (C, n = 40) groups. Behavior management techniques and behavior shaping were used for children in group E, whereas children in group C were solely guided by behavior shaping. Existence of any systemic disease or mental retardation and severe cognitive deficits based on medical chart review, psychosocial histories, or available psychological assessment data. parents refusing to sign the written informed consent, child who was referred to the hospital because of the suffering from a traumatic dental injury were the exclusion criteria of our study. The child's behavior during treatment was assessed according to Frankl behavior scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080614030N2**

Registration date: **2013-09-23, 1392/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-23, 1392/07/01

Registrant information

Name

Saba Aghaee

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of behavior management techniques to prevent unnecessary anesthesia in uncooperative children referred to dental hospital of Tabriz University, 2012

Public title

Efficacy of behavior management techniques to prevent unnecessary anesthesia in uncooperative children referred to dental hospital of Tabriz University, 2012

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: 3-6 year old uncooperative children referred to dental hospital to be treated under general anesthesia. Exclusion criteria: existence of any systemic disease or mental retardation and severe cognitive deficits based on medical chart review, psychosocial histories, or available psychological assessment data; parents refusing to sign the written informed consent; a child who was referred to the hospital because of the suffering from a traumatic dental injury; a child who needed onward referral for oral surgery; parents not being willing to consent for treatment with LA even if this was the advice of the assessor.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Blinding (investigator's opinion)
Single blinded

Blinding description
Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz Dental Faculty, Golgasht St.
City
Tabriz
Postal code
Approval date
2012-09-17, 1391/06/27
Ethics committee reference number
9252

Health conditions studied

1

Description of health condition studied
uncooperativeness
ICD-10 code
F-90
ICD-10 code description
Behavioural and emotional disorders with onset usually occurring

Primary outcomes

1

Description
Uncooperativeness
Timepoint
Before and after dental intervention
Method of measurement
Frankl behavior scale

Secondary outcomes

empty

Intervention groups

1

Description
case : applying behavior shaping and behavior management techniques such as tell show do, voice control and body restrain
Category
Behavior

2

Description
control: applying behavior shaping
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz dental faculty
Full name of responsible person
Dr. Naser Asl Aminabadi
Street address
Tabriz Dental Faculty, Golgasht St.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research department of Tabriz University of Medical Sciences

Full name of responsible person
Dr Naser Asl Aminabadi

Street address
Tabriz university, Golgasht street, Tabriz

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Research department of Tabriz 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
Department Of Pediatric Dentistry, Tabriz University of Medical Sciences

Full name of responsible person
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Position
DDS, MSc, professor

Other areas of specialty/work

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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