

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation the effects of oral Midazolam premedication on recall preoperative process in General Anaesthesia in children dentistry

Protocol summary

Summary

To decrease dental work recall in children and minimize the emotional trauma under general anaesthesia, whit used an effective premedication may facilitate a smoother induction of GA. The aim of this study are to determine efficacy dental work recall in children. In this prospective clinical trial, 60 uncooperative children are selected from those are referring for dental work under general anaesthesia. Healthy children (ASAI, ASAIL) and aged 4to10 years with refused treatment; these children are extremely uncooperative and anxious. Children are excluded from the study, if they are respiratory unstable, have any hypoxia, arrhythmia or pain in recovery room. Patients are divided in to case and control groups. The case group receives orally 0.5 mg/kg of inject able midazolam mixed with juice, 20 minutes before separation from parents. If the child is not allow venepuncture before induction of GA, inhalational anaesthetic used by combination oxygen, N2O, isofluran are doing. Standard and same monitoring and maintenance of anaesthesia during operation for all children are doing. In recovery room maintaining are performed for all patients. According to the (PADS) scale system and standard protocol. After that, ask about the recall of events from child.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101054224N9**

Registration date: **2011-08-23, 1390/06/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-23, 1390/06/01

Registrant information

Name

Nasser Kaviani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-09-20, 1390/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of oral Midazolam premedication on recall preoperative process in General Anaesthesia in children dentistry

Public title

Evaluation the effects of oral Midazolam premedication on recall preoperative process under General Anaesthesia in children dentistry

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Systemic Condition: ASAI, ASAIL;
Uncooperative children dentistry operation candidate for

general anaesthesia; Exclusion Criteria: Exist of Hypoxia; Arrhythmia; Pain in recovery room; Agitation; Nausea

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan university of Medical Sciences ethical committee

Street address

Isfahan Dental College, Isfahan Medical University, Hezar Jireeb Street

City

Isfahan

Postal code

Approval date

2010-10-18, 1389/07/26

Ethics committee reference number

390017

Health conditions studied

1

Description of health condition studied

Post operative recall

ICD-10 code

F93.8

ICD-10 code description

Other childhood emotional disorders

Primary outcomes

1

Description

Recall of process and events

Timepoint

Before medication, after anaesthesia

Method of measurement

Filling questionnaire

Secondary outcomes

1

Description

Anaesthetic technique

Timepoint

After medication

Method of measurement

Objective

Intervention groups

1

Description

Drug prescription, orally 0.5 mg/kg inject able midazolam mix with juice

Category

Prevention

2

Description

Placebo Prescription

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental College

Full name of responsible person

Sara Nazari

Street address

Shohadaye sofe street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Aminallah Tavangar

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Shohadaye sofe street
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Isfahan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
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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