Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, ASAII) 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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+98 31 1792 2858
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kaviani@dnt.mui.ac.ir

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, ASAII; 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 Jiereeb 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

Street address

Shohadaye sofe street

City

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

Isfahan Dental College- Isfahan Medical University

Full name of responsible person

Dr Naser Kaviani

Position

Doctor of Anesthesia

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan Dental College- Isfahan Medical University

Full name of responsible person

Nasser kaviani

Position

Faculty member

Other areas of specialty/work

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Web page address

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