ISRCTN13661311 https://doi.org/10.1186/ISRCTN13661311

Effectiveness of two sedative drugs on pediatric patients during dental treatment

Submission date	Recruitment status	[_] Prospectively registered
21/11/2021	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
23/11/2021	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
15/07/2022	Oral Health	

Plain English summary of protocol

Background and study aims
Dental anxiety and fear are frequent problems faced by dentists when dealing with young children. Moderate sedation is used to reduce anxiety and fear in patients. One of the most common sedative drugs used in the sedation of children is midazolam. Midazolam does not have any pain reducing effects, so it is often combined with another drug to reduce pain.
This study aims to evaluate the effects of combining midazolam with fentanyl in young dental patients.

Who can participate?
Children aged 3 - 6 years who require two visits involving sedation for completion of dental treatment.

What does the study involve?
The patients were randomly selected to receive either oral midazolam followed by intranasal Placebo or oral midazolam followed by intranasal fentanyl in the first visit and the other in the second visit. Each child will have two sedation visits with two different regimens. The period between the first and the second visit will be more than 2 weeks and less than 4 weeks. 24 hours after each sedation visit, a phone-call questionnaire is carried out about post-discharge adverse effects.

What are the possible benefits and risks of participating?
Possible benefits include the ability to provide dental treatment to the anxious uncooperative child in a safe and calm environment without causing psychological trauma to the child
Possible risks include postoperative transient behavioral changes such as (hallucination, disorientation, uncontrollable crying, agitation, restlessness, and aggressive behavior), dizziness, nausea, vomiting, and respiratory depression.; however, they have low prevalence and are not life-threatening

Where is the study run from?
Dental University Hospital, King Khaled Medical City, King Saud University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
December 2018 to October 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Roaa Alhaidari, roaa.h@hotmail.com

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRB. No. E-19-3953, CDRC No. PR 0106

Study information

Scientific Title
Intranasal fentanyl combined with oral midazolam for pediatric dental sedation: a controlled randomized blinded cross-over clinical trial

Study objectives

- Children who receive intranasal fentanyl with oral midazolam will show no significant difference in sedation and behavior levels compared to those who receive oral midazolam alone.
- Children who receive intranasal fentanyl with oral midazolam will show no significant difference in sedation onset time, working time, and side effects occurrence compared to those who receive oral midazolam alone.
- Children who receive intranasal fentanyl with oral midazolam will show no significant difference in post discharge adverse effects compared to those who receive oral midazolam alone.
- Parents/legal guardians will show no significant preference toward intranasal fentanyl with oral midazolam sedation compared to oral midazolam alone sedation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2019, The Institutional Review Board and Ethics Committee of the College of Dentistry Research Center (King Khaled Medical City, King Saud University, Riyadh, Saudi Arabia; +966-11 469-1532; rdeocampo@ksu.edu.sa), ref: IRB. No. E-19-3953, CDRC. No. PR 0106

Study design
Interventional randomized cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Sedation of pediatric patients during dental treatment

Interventions
Children between 3 and 6 years old referred to the pediatric dental clinics at Dental University Hospital, King Khaled Medical City, King Saud University for dental treatment under moderate sedation were included in the study after confirming that they satisfy the inclusion criteria and after obtaining consent from parents/legal guardians.

Children were randomly selected to receive either intranasal fentanyl (1µg/kg) or saline as placebo in the first visit and the other in the second visit along with oral midazolam (0.7mg/kg). Then, video recording was done for all sedation visits to evaluate sedation and behavior status, onset of sedation, working time, and occurrence of any side effects.

Then, a questionnaire regarding post discharge adverse effects of sedation and parents/legal guardians' satisfaction and preference was delivered 24 hours after both sedation visits through a phone call with the parents/legal guardians.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Midazolam, fentanyl

Primary outcome measure
1. The sedation scores were recorded using the Modified Observer's Alertness/ Sedation Scale (MOAA/S) after sedation at each visit
2. The behavior scores were recorded using a four-point scale (4 = combative, disoriented, or excited; 3 = moderately agitated; 2 = not calm; and 1 = calm) after sedation at each visit
3. Post-discharge adverse effects and parental satisfaction and preference were evaluated using a questionnaire 24 hours after each visit

Secondary outcome measures
1. The onset of sedation was measured as the minimum time interval required for child to become drowsy after administering the oral midazolam at each visit
2. The time that elapses between the child becoming drowsy (sedation score = 4) and when the patient become alert and awake (sedation score = 5 or 6) was measured as the working time at each visit

Overall study start date
11/12/2018

Completion date
22/10/2020

Eligibility

Key inclusion criteria
1. 3 - 6 years old
2. ASA I
3. Frankl behaviour rating scale 1 or 2
4. Mallampati score I or II
5. Brodsky tonsillar size scoring 0 or 1 or 2
6. Children within the normal range of weight
7. Children who needed two sedation visits for completion of dental treatment
8. Children who needed a comparable dental treatment (as regards restorations, pulp treatment, crowns, extraction) on both sides of the same jaw.

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
3 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
32

Total final enrolment
32

Key exclusion criteria
1. Children with learning difficulties or mental disabilities
2. Children with active upper respiratory tract infection, any history of a recent cough or cold (less than 2 weeks)
3. Children with a known allergy or hypersensitive reaction to either midazolam or fentanyl
4. Children at risk of airway obstruction
5. Children with any intranasal pathology or congenital anomaly
6. Children with a previous history of moderate sedation

Date of first enrolment
26/09/2019

Date of final enrolment
22/10/2020

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Dental University Hospital, King Khaled Medical City, King Saud University
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Sponsor information

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University/education

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ROR
https://ror.org/02f81g417

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
26/11/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (Roaa Alhaidari, e-mail: roaa.h@hotmail.com, SPSS data, the data will become available upon request, written consent from participants was obtained, no ethical or legal restrictions).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Post-discharge effects and parents' opinions	01/02/2022	15/07/2022	Yes	No