ISRCTN46437306 https://doi.org/10.1186/ISRCTN46437306

The effect of an inhalation sedation familiarization visit on children's dental behavior

Submission date
26/03/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dentists use a wide variety of techniques to reduce the fears of children and increase their cooperation while receiving dental treatment. Laughing gas (inhalation sedation) is a proven safe method for reducing children's dental anxiety and has been used worldwide for decades. It is a light form of sedation and is a mixture of nitrous oxide and oxygen breathed through a nose-piece. This helps the child to feel relaxed and accept treatment. Rather than starting the sedation at the first dental visit, many clinicians suggest an introductory/familiarization visit. There is controversy regarding the use of introductory/familiarization visits for dental sedation treatment pathways for children. The acclimatization visit can be defined as "one in which sedation only is provided and no, or minimal dental treatment, is carried out". This may increase acceptance based on desensitization and acclimatization principles underpinning many behavior management techniques. This study aims to help dentists and dental care providers to identify whether a laughing gas inhalation sedation introductory/familiarization visit is effective at making anxious children more relaxed and accepting of dental treatment, or not.

Who can participate?
Children aged 5-15 referred for pediatric specialist treatment in Dubai Dental Hospital in need of treatment under inhalation sedation

What does the study involve?
Participants are randomly allocated to one of two groups: group A where the parent/guardian and child attend a visit for tooth brushing advice (no treatment) and laughing gas is used and introduced to familiarize the child, or group B where the parent/guardian and child attend for tooth brushing advice (no treatment) and a discussion of inhalation sedation without actual usage of laughing gas. The actual dental treatment for both groups starts at the second visit. To record anxiety-related changes (heart beats, pulse etc), the child is asked to wear a wrist band to measure physiological changes for 15 minutes before dental treatment and throughout the treatment sessions. In addition, salivary samples (1.5 to 2 ml) are collected at standardized three times for each participant to measure the levels of salivary Alpha Amylase and Cortisol:
1. At the start of the initial visit
2. 15 minutes before the start of second visit treatment
3. 15 minutes after the completion of second visit treatment

What are the possible benefits and risks of participating?
There may be no direct benefit to the child, other than the benefit of laughing gas relaxation. The study will find out if an inhalation sedation (laughing gas) introductory or familiarization visit is effective in making children more relaxed and accept dental treatment. Please note that the cost of the initial visit will be covered by a research grant because many insurance companies do not cover the cost of the introductory or familiarization visit. Possible risks: nausea and vomiting in 1-10% of cases and occasional headache. The results of this study are intended to be used for research purposes, publication in dental journals and presentations at conferences. There will be no mention of specific individuals.

Where is the study run from?
Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences, Dubai, United Arab Emirates

When is the study starting and how long is it expected to run for?
February 2018 to October 2023

Who is funding the study?
The study is funded by an internal research grant from the Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences

Who is the main contact?
Dr Mawlood Kowash
Mawlood.kowash@mbru.ac.ae

Contact information

Type(s)
Scientific

Contact name
Dr Mawlood Kowash

ORCID ID
https://orcid.org/0000-0002-4721-3789

Contact details
Dubai Healthcare City
Building 34
Dubai
United Arab Emirates
505055
+971 (0)505939004
mawlood.kowash@mbru.ac.ae

Additional identifiers

Protocol serial number
MBRU-IRB-2018-014

Study information

Scientific Title
A single-center investigator-blinded randomized parallel-group study to investigate the effect of an acclimatization visit on children's behavior during inhalation sedation in a United Arab Emirates pediatric dentistry postgraduate setting

Acronym
Dental inhalation sedation study

Study objectives
Children's behaviors and anxiety levels are better in the study group compared to those in the control group, who will not be offered a familiarization visit and managed routinely.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/06/2018, Mohammed Bin Rashid University of Medicine and Health Sciences Ethical Board (PO Box 505055, Dubai, United Arab Emirates), Tel: +971 (0)43838706, Email: irb@mbru.ac.ae, ref: MBRU-IRB-2018-014

Added 23/07/2019:
Note: Approval of amendment in the original protocol (i.e. collecting salivary samples for determination of salivary amylase and cortisol levels) has been granted on 22/7/2019.

Primary study design
Interventional

Study design
Single-center single-blind (to dentist providing treatment) parallel-group randomized controlled two-arm clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental anxiety in children

Interventions
After baseline examination by the clinical team, eligibility verification, participant's assent and parents'/guardian's consent submission, participants will be randomized to the two study groups (30 patients per group). Block randomization with a 1:1 allocation will be performed by the PI with the aid of a computer program and help of statistician (AH), to either study or control group:
1. Study Group. Families (children and parents) would attend a visit for prevention and inhalation sedation will be introduced and tried.
2. Control Group. Families would attend for prevention visit and discussion of inhalation sedation only.
The actual dental treatment for both groups will commence at the second visit.

At the initial visit the sedation need score will be recorded using the Pediatric Indicator of Sedation Need (p-SION). As a component of p-SION it will include anxiety measured using the Modified Dental Anxiety Scale (MDAS). Treatment for both groups will commence at 2nd visit and the following outcomes will be recorded:
1. Completion of dental treatment
2. Anxiety Scores at baseline and after treatment using MDAS at different time points and physiological anxiety-related changes will be recorded using E4 wrist bands. The wrist band will be placed 15 minutes before the patient comes into the surgery for treatment and will be taken off 15 minutes after the completion of treatment. This will enable recording physiological parameters continuously before, during and after the dental treatment. E4 Wrist bands will provide Electrodermal Activity (EDA) also known as Galvanic Skin Response (GSR), Blood Volume Pulse (BVP), Acceleration, Heart Rate (HR), and Temperature. E4 wrist bands are small, very similar to wearing a watch and we do not anticipate any increase in anxiety in children as a result of wearing these wrist bands. The E4 wrist band was approved by U.S. Food and Drug Administration as a medical device. It is used in a wide range of research settings with configurations for palmar skin conductance measurement or the use of gelled electrodes secured under the band. For more information about E4 wrist band, please refer to the link below: https://store.empatica.com/products/e4-wristband?variant=39588207747
3. Behavior score during treatment (Frankl score). Parental/children's satisfaction and acceptance questionnaire. Parents and children will be requested to complete a short questionnaire (Appendix II) to measure their acceptance/satisfaction of dental treatment with or without acclimatization visit.

Added 23/07/2019:
4. Salivary samples will be collected and analyzed using Expanded Range High Sensitivity Salivary Amylase and Cortisol Enzyme Immunoassay Kit (Bio Medical Scientific Services LLC ISO 9001: 2008 Registered Firm. Certificate No.: DQU-12422) with the help of Mr Athiq Ahmed Wahab at MBRU laboratory. The samples will be analyzed to determine the anxiety levels of the participants. A considerable amount of literature has been published on saliva as a non-invasive biological biomarker of stress. One of the major enzymes of saliva is salivary alpha-amylase (SAA). Synthesized and secreted by acinar cells of the salivary glands, mainly the parotid gland. Several studies have reported the correlation between dental anxiety and the increase in salivary alpha-amylase and cortisol levels.
Salivary samples (1.5 to 2 ml) will be collected at standardized 3 times for each patient:
1. At the beginning of the initial visit
2. 15 minutes before the start of second visit treatment
3. 15 minutes after the completion of second visit treatment

Intervention Type
Procedure/Surgery

Primary outcome(s)
Behavior and anxiety levels:
1. Physiological parameters measured by:
1.1. The E4 wrist band during the second (treatment) visit, which is approximately one week after the initial visit. The child will wear the watch for 15 minutes prior to dental treatment while sitting with parent/guardian in the waiting room and continuously during the treatment session (Added 23/07/2019) 1.2. Salivary amylase and salivary cortisol levels measured using Expanded Range High Sensitivity Salivary Amylase and Cortisol Enzyme Immunoassay Kit at the beginning of the initial visit, 15 minutes before the start of second visit treatment, and 15 minutes after the completion of second visit treatment

2. Anxiety scores using a component from the Indicator of Sedation Need (IOSN) at baseline (initial visit) and after treatment (second visit)
3. Behaviour score recorded using Frankl behaviour rating scale at the end of initial (first) visit and end of second treatment visit

Key secondary outcome(s)
The beneficial effect of the acclimatization inhalation sedation visit, assessed using:
1. Satisfactory completion of the required dental treatment at the end of second visit
2. Children's and parents' acceptance of dental treatment with or without acclimatization visit at the end of second visit
Measured using guardian/child quantitative questionnaire and records from clinical notes

Completion date
15/10/2023

Eligibility

Key inclusion criteria
1. Healthy children aged 5-15 years in need of dental treatment under inhalation sedation
2. No learning disabilities
3. Suitable for nitrous oxide/oxygen inhalation sedation (IHS)
4. United Arab Emirates (UAE) and non-UAE nationals' parents and children will be eligible to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
All

Key exclusion criteria
1. Children with special healthcare needs and/or medically compromised
2. Children who their parents refuse to consent
3. Those with complex medical histories ASA III and ASA IV
4. Children with a known diagnosed psychiatric disorder
5. Children younger than five years and older than 15 years

Date of first enrolment

01/05/2019

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

United Arab Emirates

Study participating centre
Dubai Healthcare City
Building 34
Dubai
United Arab Emirates
505055

Sponsor information

Organisation
Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences

ROR
https://ror.org/05g48k331

Funder(s)

Funder type
University/education

Funder Name
Hamdan Bin Mohammed College of Dental Medicine, Mohammed Bin Rashid University of Medicine and Health Sciences

Results and Publications

Individual participant data (IPD) sharing plan

All the anonymous collected data will be shared upon request to the primary investigator Mawlood Kowash (mawlood.kowash@mbru.ac.ae; mkowash@gmail.com) once the study is completed. The data will be stored for 5 years after the final publication to be shared upon request. There will be no mention of patient identifiers. Each participant will be given a unique code number. The list connecting the participants' identifiers (i.e. name/contact details) with the study code number will be kept in a locked cabinet. Only the PI will have access to this list. Clinical recording sheets, questionnaires and E4 wrist band physiological data will only be labelled using the code number. When the study is completed, and the data have been analyzed, the participants' list will be destroyed. No personal information will be used in any report or publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/08/2019	17/06/2025	Yes	No
Protocol file			29/03/2019	No	No