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Parents/caregivers and their children's experience of dental general anaesthesia

Submission date
11/02/2023

Recruitment status
No longer recruiting

Registration date
17/03/2023

Overall study status
Completed

Last Edited
17/03/2023

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
Dental general anaesthesia is a widely used treatment for various oral health problems, particularly in children who cannot tolerate invasive procedures while awake due to pain or infections. However, there is limited research on the experiences of both parents and children with dental treatment performed under general anaesthesia or with the anaesthesia itself, which can result in inadequate communication, support, and ineffective recovery from this potentially traumatic experience. The aim of this study is to gain a better understanding of the expectations, experiences, and perspectives of children and their parents or caregivers regarding the communication and support they received during dental procedures where general anaesthesia is used.

Who can participate?
Parents or caregivers of children between 6 to 16 years old who have been referred by their dentist for dental general anaesthesia assessment and attending for routine or urgent care

What does the study involve?
The study involves collecting information through three stages using two methods. In Stage 1, the researchers will conduct pre-procedure semi-structured interviews with the parent or caregiver, which can be in person or virtually. During the interview, open-ended questions will be used, and the interview will be recorded either through a Dictaphone voice recorder or the Teams software. The child is welcome to attend the interview, but it is optional.
In Stage 2, parents or caregivers will be asked to record their thoughts and reflections about the procedure through audio diaries using their mobile phones. The research team will provide guidance on how to record and send the audio, and reminders will be given if needed.
In Stage 3, researchers will conduct follow-up interviews with the parents or caregivers and their child up to 3 months after the operation. This will be done in person or online, and the same data collection methods used in Stage 1 will be followed. The child is welcome to attend the interview, but it is optional.

What are the possible benefits and risks of participating?
The participants will not personally benefit from the study results, but the information gathered will be used to improve support and communication for families who undergo Dental General

Anaesthesia in the future. There is no expected harm from this observational study, and interviews will be conducted virtually to reduce inconvenience to participants. However, talking about the experience of having dental general anaesthesia may be difficult and could cause some participants to feel upset or distressed. The research team is prepared to handle these situations. Participants will receive a £30 voucher for each interview they attend and a £40 voucher when they complete the audio diary recording.

Where is the study run from?
Cardiff University Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2022 to March 2024

Who is funding the study?
Oral & Dental Research Trust (UK)

Who is the main contact?
Dr Waraf Al-Yaseen, al-yaseenw1@cardiff.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
322812

Protocol serial number
IRAS 322812

Study information

Scientific Title
An exploration of parents/caregivers and their children's experience of undergoing dental general anaesthesia. a multi-method longitudinal qualitative study

Study objectives
General anaesthesia is a commonly used method to facilitate dental treatment provision for children when the planned care cannot be provided with local anaesthesia or behaviour management techniques alone. This type of anaesthesia, referred to as Dental General Anaesthesia (DGA), is typically conducted by a multi-disciplinary medical and dental team led by specialists or consultants in paediatric dentistry within children's hospitals or dedicated dental hospital theatres. In the UK, DGA services usually provide a range of dental procedures, mainly extractions and restorations, with local anaesthesia and sedation also given. After the DGA course of treatment, children are usually discharged to their general dental practitioner for continuing preventive care.

DGA is the most common reason for UK children to be hospitalized, with around 1-2 children out of every 100 undergoing DGA in England in 2020-2021 (n=22,459 DGA procedures). It is mainly used to manage dental caries, a preventable yet common disease in children. Although DGA is necessary, it is an invasive procedure and can have long-term adverse consequences, such as nightmares and negative memories. Studies of children undergoing GA for other medical conditions have shown that 35% experience separation anxiety for months post-operatively. To mitigate these negative effects, children should be prepared and cared for through well-planned protocols that include providing the right information, effective communication, and adequate follow-up. However, this is not always the case in practice. One study showed that some children undergoing DGA did not know much about the procedure, the venue, or whether their parents would accompany them to the operating theatre. Another English study revealed negative feelings and wide variations in service, environment, and communication across six hospitals from the perspectives of child patients and their parents. There is therefore a need for more research on the communication and support provided to children and their families during DGA, as most existing research focuses on clinical outcomes and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-method longitudinal qualitative observational study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Children having dental treatment under Dental General Anaesthesia (DGA)

Interventions
This study will be a long-term investigation that will use a multi-method, qualitative approach to gather information. The study will focus on understanding people's experiences and perspectives. Data will be collected from parents or caregivers and children (aged 6 years or older) who undergo dental procedures using general anaesthesia. The methods of data collection will include in-depth interviews before and after the procedure, as well as audio recordings made by the parents during the procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The perceived quality of the communication and support provided for the families when their child is having dental treatment under general anaesthesia (DGA), measured qualitatively through interviews and collecting diaries from the parent before, during and after (up to a week) the planned operation

Key secondary outcome(s))
1. Recommendations for further research to enhance the support and communication to families while their child is undertaking DGA, measured during the analysis stage by assessing current research gaps and recommending evidence-based interventions to be designed and evaluated
2. The suitability of using longitudinal audio diaries (LADs) as a data collection method, measured during stage 2 of data collection by assessing the level of engagement and the frequency of the audio recording sent

Completion date
01/03/2024

Eligibility

Key inclusion criteria
The researchers will identify and recruit children and their parents/caregivers who are attending Cardiff Dental Hospital, Paediatric Dentistry Department and where the child has treatment planned to be carried out under a DGA as part of their care plan.

Children:
1. Between 6-16 years old
2. Referred by their dentist for DGA assessment and attending for routine or urgent care
3. No restriction on their American Society of Anesthesiologists (ASA) score
4. Parent considers that the child can understand enough to communicate verbally (should they choose to) for the interview
5. Can communicate in English or Arabic
6. Can provide permission for their parents to participate
7. Can sign an age-appropriate assent form

Parents/caregivers:
1. Can be either the biological, step or adoptive parents, and must live with the child and have legal guardianship

2. Can read and communicate in English or Arabic
3. Can give informed written consent to participate
4. Have any type of mobile phone with a recorder function

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
Children:
1. Younger than 6 years old
2. Unable to understand English or Arabic
3. Unable or unwilling to provide permission to parents to take part in the study

Parents/caregivers:
1. Cannot provide valid informed consent
2. Do not have a mobile phone with recording capabilities. if this is the case, they will be excluded only from stage 2 of the study, which involves longitudinal diary recording during the operation

Date of first enrolment
01/04/2023

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

University Dental Hospital NHS Trust
Heath Park
Cardiff
United Kingdom
CF14 4XY

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Oral & Dental Research Trust

Results and Publications

Individual participant data (IPD) sharing plan
The IPD will be made available to qualified researchers for the purpose of conducting legitimate scientific investigations while ensuring the protection of participant privacy and confidentiality.

The IPD to be shared includes demographic information, baseline characteristics, study anonymised transcripts, outcome data, and any other relevant data collected as part of the study. All patient-identifiable information will be removed from the data prior to sharing, to ensure that no individual participant can be identified.

Researchers interested in accessing the IPD must meet the following criteria:
1. Obtain approval from an independent ethics committee for their proposed research project.
2. Provide a clear and scientifically legitimate purpose for accessing the IPD.
3. Sign a data access agreement that outlines the terms and conditions for using the data and protecting participant privacy and confidentiality.

The IPD will be stored in a secure manner using secure file storage and transmission mechanisms. Access to the IPD will be restricted to authorized personnel only and will be governed by strict access controls.

Researchers who access the IPD are required to:
1. Acknowledge the source of the data in any publications or presentations arising from their use of the data.
2. Do not use the data for commercial purposes.
3. Do not share the data with unauthorized third parties.
Use the data only for the purposes outlined in the approved research project and data access agreement.

Researchers interested in accessing the IPD should contact Waraf Al-yaseen (al-yaseenw1@cardiff.ac.uk). Requests for access to the IPD will be reviewed by the management team to ensure that the access criteria have been met and that the data will be used in accordance with the policies and procedures for protecting participant privacy and confidentiality.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	07/02/2023	17/02/2023	No	No