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Behavior of children during dental care using a rubber dam or cotton roll to isolate the tooth

Submission date	Recruitment status	[_] Prospectively registered
25/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2023	Oral Health	

Plain English summary of protocol

Background and study aims
A dental dam is used in dentistry to isolate the tooth being operated on from the rest of the mouth to improve dentist working conditions and for patient protection. The aim of this study is to analyze the behavior of children during dental care with or without a dam.

Who can participate?
All children with temporary molar tooth decay

What does the study involve?
Patients are randomly allocated to receive treatment using the rubber dental dam or using a cotton wool dam. During the procedure the behavior and heart rate of the patient is measured.

What are the possible benefits and risks of participating?
None

Where is the study run from?
CHU Saint-Pierre (Belgium)

When is the study starting and how long is it expected to run for?
October 2017 to March 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Tania Vanhee
Tania.Vanhee@ulb.be

Contact information

Type(s)
Scientific

Contact name
Dr Tania Vanhee

ORCID ID
https://orcid.org/0000-0001-7608-4368

Contact details
Université Libre de Bruxelles
Faculté de Médecine
CP 622 808 Route de Lennik
Brussels
Belgium
1070
+32 (0)478613102
Tania.Vanhee@ulb.be

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
B076201734515

Study information

Scientific Title
The effect on behavior and heart rate of using isolation with a rubber dam or isolation with cotton rolls in children with caries on primary molars, a randomized study

Study objectives
This study aims to determine the behavioral and physiological indicators of stress in children during dental care with or without a rubber dam with the hypothesis that rubber dam decreases stress. The null hypothesis is that there is no difference between the outcomes measured in the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2017, Ethics committee of CHU Saint-Pierre (322, rue Haute, 1000, Brussels, Belgium; no telephone number provided; christopher_vandenberghe@stpierre-bru.be), ref: B076201734515

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stress in children during dental care

Interventions
Based on the sample size of comparable studies, a cohort of 51 children, 30 boys and 21 girls, from 3 to 10 years old is recruited form patients consulting in the pediatric dentistry department of CHU Saint-Pierre, César de Paepe site (Brussels, Belgium). Patients needing operative treatment on at least one primary molar are eligible to participate. Children with infected or mobile decayed teeth as well as those outside the age range studied are excluded.
The patients included in the study are randomized at the beginning of the day by random draw and assigned either: the test group with rubber dam and the control group with cotton roll isolation. Treatments are performed by 12 practitioners belonging to the pediatric dentistry team. All treatments are followed by a single observer who collected the data.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Behavior measured using the modified Venham hetero-evaluation scale at five different time points (T0 to T4). T0: patient installed in the dental chair, T1: during local anesthesia, T2: before placing isolation, T3: with isolation installed and T4: during the treatment

Key secondary outcome(s))
Heart rate recorded using a Digital Finger Pulse Oxygen Saturation Monitor OLED display (Elera, China) at five different time points (T0 to T4). T0: patient installed in the dental chair, T1: during local anesthesia, T2: before placing isolation, T3: with isolation installed and T4: during the treatment

Completion date
07/03/2018

Eligibility

Key inclusion criteria
Patients aged 3 - 10 years, needing operative treatment on at least one primary molar

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
10 years

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Children with infected or mobile decayed teeth
2. Outside the age range studied

Date of first enrolment
17/11/2017

Date of final enrolment
07/03/2018

Locations

Countries of recruitment
Belgium

Study participating centre
CHU Saint-Pierre
Pediatric Dentistry department
Stomatology service
César de Paepe site
11, Alexiensstreet
Brussels
Belgium
1000

Sponsor information

Organisation
Université Libre de Bruxelles

ROR
https://ror.org/01r9htc13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2021	28/02/2023	Yes	No
Basic results		02/08/2021	02/08/2021	No	No
Participant information sheet			08/01/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes