

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

Submission date 25/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/02/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

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 from 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 measure

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

Secondary outcome measures

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

Overall study start date

09/10/2017

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

Age group

Child

Lower age limit

3 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

51

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

Sponsor details

Faculté de Médecine
808 Route de Lennik
Brussels
Belgium
1070
+32 (0)25556799
admin.medecine@ulb.be

Sponsor type

University/education

Website

<http://www.ulb.ac.be/>

ROR

<https://ror.org/01r9htc13>

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

01/01/2021

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?
Participant information sheet			08/01/2021	No	Yes
Basic results		02/08/2021	02/08/2021	No	No
Results article		04/08/2021	28/02/2023	Yes	No