

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

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

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## Contact information

Type(s)

Scientific

**Contact name**

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**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  
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### 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?
<a href="#">Participant information sheet</a>			08/01/2021	No	Yes
<a href="#">Basic results</a>		02/08/2021	02/08/2021	No	No
<a href="#">Results article</a>		04/08/2021	28/02/2023	Yes	No