

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

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