

Dental sealant quality, chair time, and patients' preference of three isolation techniques

Submission date 13/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

During dental work, it is common to isolate the tooth from the rest of the person's mouth, which allows the tooth to be repaired dry and with relatively less exposure to bacteria in the mouth. This randomized clinical trial aimed to evaluate the patient's preference and chair time needed under three isolation techniques (Isolite system, rubber dam isolation, and cotton roll isolation).

Who can participate?

Children aged 6-15 years requiring four sealants on the first or second permanent molars attending the pediatric dental clinics at King Saud University in Saudi Arabia

What does the study involve?

Each participant received sealants on three random first or second permanent molars using three isolation techniques. The time required for sealant placement was recorded for each technique. Following sealant placement, an interview-based questionnaire was administered to the participants to evaluate their preference regarding the isolation techniques.

What are the possible benefits and risks of participating?

All participants will benefit from oral hygiene instructions, examination, prophylaxis and pit and fissure sealant placement. No risks.

Where is the study run from?

King Saud University (Saudi Arabia)

When is the study starting and how long is it expected to run for?

February 2018 to February 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Rahif Mattar, rahifmattar@hotmail.com

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Comparison of the quality of fissure sealant and the preference of pediatric dental patients with three different isolation techniques

Study objectives

1. The Isolite system will have a higher patient preference when compared to Rubber Dam isolation and Cotton roll isolation
2. The chair time using Isolite system will have a shorter chair time than that using Rubber dam isolation and Cotton roll isolation
3. The quality of pit and fissure sealant using Isolite system will be higher than that using Rubber dam isolation and Cotton roll isolation

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 20/11/2018, The Institutional Review Board (King Saud University, PO Box 7805, Riyadh, Saudi Arabia; +966-11 469-1531; rdeocampo@ksu.edu.sa), ref: E-18- 3376
2. Approved 29/01/2020, The College of Dentistry Research Center (College of Dentistry, King Saud University, PO Box 7805, Riyadh, Saudi Arabia; +966-11 469-1532; irb.medksu@hotmail.com), ref: PR 0103

Study design

Split-mouth randomized clinical trial single center

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Isolation techniques for dental treatment

Interventions

Forty-eight children aged 6 - 15 years participated according to inclusion/exclusion criteria. They were randomized by using simple block random allocation to ensure a balanced randomization for each isolation system using random numbers that were generated using a computer program (MedCalc). The sealed envelope technique was used.

Each participant received three pit and fissure sealants on their permanent first or second molars using three different isolation techniques (Isolite system Rubber Dam isolation and Cotton roll isolation) according to randomization by a single operator. The time was measured by a stop watch, the quality of sealants were assessed by a blinded evaluator. Following sealant placement, an interview-based questionnaire was administered to the participants to evaluate their preference regarding the isolation techniques.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Isolite System by Zyris

Primary outcome measure

Measured at a single time point for each technique:

1. Sealants quality was evaluated according to Simonsen's criteria
2. Sealant chair time was measured using a stopwatch
3. Patients' preference was measured according to a novel validated questionnaire

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

12/02/2018

Completion date

23/02/2021

Eligibility

Key inclusion criteria

1. Normal healthy patient with ASA 1 according to the American Society of Anesthesiologists Classification
2. Children aged 6 - 15 years, willing to participate in the study
3. Legal guardian accepts the participation of the child in the study
4. Participant must require 4 pits and fissure sealants on all first or second permanent molars with an International Caries Detection and Assessment System (ICDAS) score of 0 - 2, and 5)
Arabic or English speaker children

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

48

Total final enrolment

48

Key exclusion criteria

1. Special Needs children
2. Conditions requiring emergency dental treatment (abscess, draining sinus, cellulitis)
3. Partially erupted permanent first or second molars
4. Enamel/Dentin anomalies
5. Uncooperative children, Frankl Behavior Rating Scale of 1 or 2
6. Children with a severe gagging reflex
7. Children allergic to latex
8. Children with recent dental radiographs taken but not available on the computer system

Date of first enrolment

25/11/2018

Date of final enrolment

02/01/2020

Locations

Countries of recruitment

Saudi Arabia

Study participating centre**King Saud University**

Department of Pediatric Dentistry and Orthodontics

College of Dentistry

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Sponsor information

Organisation

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Sponsor type

University/education

Website

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ROR

https://ror.org/02f81g417

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

01/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from (Rahif Mattar, e-mail: rahifmattar@hotmail.com, excel sheet, the data will become available upon request, written consent from participants was obtained, no ethical or legal restrictions).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/05/2021	15/06/2021	Yes	No
Results article	fissure sealant retention results	11/05/2022	10/10/2022	Yes	No