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

Submission date
13/05/2021

Recruitment status
No longer recruiting

Registration date
14/05/2021

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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
King Saud University

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Sponsor type
University/education

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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	fissure sealant retention results	25/05/2021	15/06/2021	Yes	No
Results article		11/05/2022	10/10/2022	Yes	No