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The usage of different sealing materials for prevention of pit and fissure dental caries

Submission date	Recruitment status	[_] Prospectively registered
02/04/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/04/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/11/2020	Oral Health	

Plain English summary of protocol

Background and study aims
Children are at a greater risk for the development of dental caries (tooth decay) due to their diet, their permanent teeth erupting, and deep pits and fissures in the teeth which favor retention of food debris and dental plaque. Different pit and fissure sealants are used to treat caries such as composite resin, glass ionomer and resin infiltrant. There is not enough evidence about the effectiveness of resin infiltrant as a pit and fissure sealant. No consensus exists about its common use in clinical practice. In addition, investigations of the preventive effectiveness of different commercially available sealant materials are limited. The aim of this study is to assess the effectiveness of resin infiltrant (ICON) and compare its effectiveness in prevention of pits and fissures caries with two commercially available and clinically recommended fissure sealants.

Who can participate?
School children aged 6-8 years old

What does the study involve?
Participants are randomly allocated to be treated with different pit and fissure sealant materials for prevention of pit and fissure caries in their permanent first molars. Their teeth are then assessed after 1, 3, 6, 12, 18 and 24 months.

What are the possible benefits and risks of participating?
The expected benefits are prevention of dental caries and good dental health, also this trial will improve the knowledge of children and schools about the importance of prevention of dental caries. There are no anticipated risks or side effects.

Where is the study run from?
Mansoura University (Egypt)

When is the study starting and how long is it expected to run for?
July 2016 to October 2019

Who is funding the study?
Mansoura University (Egypt)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
149-2015

Study information

Scientific Title
The efficacy of different sealant modalities for prevention of pits and fissures caries. A randomized clinical trial

Acronym
Fissure sealant AND caries prevention

Study objectives
The present clinical trial aimed to:
1. Evaluate the efficacy of resin infiltrant (Icon) in prevention of pits and fissure caries
2. Evaluate the efficacy of Icon combination with nano particle resin sealing material (Seal It) in prevention of pits and fissure caries
3. Compare the efficacy of different pit and fissure sealants modalities used for prevention of pit and fissures caries in vivo

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 16/01/2016, institutional ethical committee, Faculty of Dentistry, Mansoura University (El-Gomhoria St., Dakahlia Governorate, 35516, Egypt; Tel: +20 (0)50 2248512; Email: boshra@mans.edu.eg), IRB number: 149-2015

Study design
Single-center randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pit and fissure dental caries

Interventions
The trial involved four groups of first permanent molars of schoolchildren aged 6-8 years. The study was carried out in a split-mouth design.

Randomization: The selected molars were randomly classified into four groups according to treatment modalities.

Blinding: Well-trained and calibrated external examiner who was blind to study design and materials used did the clinical examination and evaluation of sealant retention. The collected data was analysed by an external statistician.

Three different pit and fissure sealant materials were used in the present trial:
1. ICONTM; infiltrant resin (DMG Dental Materials, Hamburg, Germany)
2. Seal It; nanoparticle composite based pit and fissure sealant (Spident- 2115 Linwood Ave. Fort Lee – NJ07024)
3. GCP glass seal; nanoparticle glass ionomer-based pit and fissure sealant (GCP Dental | Boelewerf 32 | 2987 VD Ridderkerk)
4. The fourth group received a combination of resin infiltrant and composite resin fissure sealant (ICON+ SEAL IT)

For ethical reasons, all participants with dental problems were referred for necessary treatment in the dental clinic of the Pediatric Dentistry Department, Faculty of Dentistry, Mansoura University.

Baseline scores and follow up examination of dental caries in pits and fissures of molars under study recorded according to ICDAS criteria. All materials used to seal pits and fissures with strict adherence to individual manufacturer's instructions including slow speed handpiece for cleaning of the surface with fluoride free pumice/water slurry, cotton roll isolation, etching agent and fourhanded technique application.

Intervention Type
Other

Primary outcome measure
Measured at 1, 3, 6, 12, 18 and 24 months:
1. Sealant retention evaluated according to a modified version of the Colour, Coverage and Caries (CCC) sealants evaluation system and classified into four scores: score A = sealant is present in all the fissure system; score B = sealant is present in more than 50% of the fissure system; score C = sealant is present in less than %50 of the fissure system; score D = absent sealant.
2. Dental caries evaluated using mouth mirror and blunt probe
The same external examiner who was blinded to the study design did the evaluation of caries incidence and sealant retention

Secondary outcome measures
Presence of dental caries assessed according to ICDAS criteria at 1, 3, 6, 12, 18 and 24 months. The grades 0, 1 and 2 were recorded while scores 3, 4, 5 and 6 were recorded as one category named other grades more than grade 2. At the end of the trial, in the event of new caries development and sealant failure, the fissures were either resealed or restored.

Overall study start date
01/07/2016

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Children free from systemic diseases
2. All four permanent first molars should be fully erupted
3. All molars had sound, non-cavitated grade 0, 1 or 2 caries according to ICDAS caries diagnostic criteria

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants

44 children (176 permanent molars)

Total final enrolment
44

Key exclusion criteria
1. Children with hypo-plastic permanent first molar, proximal caries, occlusal carious lesions more than grade 2 or any developmental anomalies
2. Children who felt not to be sufficiently cooperative to allow sealant placement
3. Children with systemic disorders

Date of first enrolment
25/08/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Egypt

Saudi Arabia

Study participating centre
Mansoura University
El-Gomhoria St.
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Sponsor information

Organisation
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Sponsor type
University/education

Website
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ROR
https://ror.org/01k8vtd75

Funder(s)

Funder type
University/education

Funder Name
Mansoura University

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Egypt

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Wahdan Elkwatehy (elkwatehywahdan@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/03/2019	03/11/2020	Yes	No