

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

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<b>Registration date</b> 05/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/11/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## 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?  
Dr Wahdan Mohammad Abdelghany Elkwatehy  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Wahdan Elkwatehy

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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.

Faculty of Dentistry

El-Mansoura

Saudi Arabia

35516

## **Sponsor information**

**Organisation**

Mansoura University

**Sponsor details**

El-Gomhoria St.

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**Sponsor type**

University/education

**Website**

<http://www.mans.edu.eg/>

**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?
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[Results article](#)

results

01/03/2019

03/11/2020

Yes

No