

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### comparison of clinical success of Embrace fissure sealant whit Helioseal

#### Protocol summary

##### Summary

to compare the clinical success of a new hydrophilic resin-based fissure sealant (Embrace Wet Bond) and a conventional hydrophobic resin-based fissure sealant (Helioseal F), Forty children (6 to 9 year old) referred to pediatric ward of Tehran Azad University of Dentistry randomized to 2 subgroups: Embrace fissure sealant (Pulpdent) or Helioseal. For each group surfaces were cleaned and dried, then etched for 15 seconds. Excess water was removed leaving the surface slightly moist. Sealant was applied from cusp to cusp without covering marginal ridges and light cured for 20 seconds using a LED light. Patients will be evaluated after 3, 6, 12, 18 months for the following criteria: any evidence of caries, marginal adaptation, surface smoothness and retention

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014072618601N1**

Registration date: **2015-02-08, 1393/11/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-02-08, 1393/11/19

##### Registrant information

###### Name

Nazanin Zangeneh

###### Name of organization / entity

Islamic Azad University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4421 0303

###### Email address

den\_zangeneh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Islamic Azad University of Tehran

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2016-04-20, 1395/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of clinical success of Embrace fissure sealant whit Helioseal

##### Public title

the evaluation of clinical success of a hydrophilic fissure sealant

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

6 to 9 year old children referred to pediatric ward of Tehran Azad University of Dentistry who have following criteria include: the presence of two fully erupted first permanent molars in both sides of the jaw; having an acceptable hygiene training plan; compliant patient during treatment and follow ups; lack of caries and anomalies; lack of hypocalcification, lack of previous treatment on the first molars; possibility of acceptable isolation; lack of medical history or any drug effective on saliva flow; lack of allergy to restorative materials

##### Age

From **6 years** old to **9 years** old

##### Gender

Both

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran Azad University of Dentistry

##### Street address

10th neyestan, Pasdaran

##### City

Tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

11-ع

## Health conditions studied

### 1

#### Description of health condition studied

Dental caries

#### ICD-10 code

K02.9

#### ICD-10 code description

Dental caries, unspecified

## Primary outcomes

### 1

#### Description

retention

#### Timepoint

3,6,12,18 month

#### Method of measurement

with explorer and visual

### 2

#### Description

marginal adaptation

#### Timepoint

3,6,12,18 month

#### Method of measurement

with explorer and visual

### 3

#### Description

caries

#### Timepoint

3,6,12,18 month

#### Method of measurement

with explorer and visual

### 4

#### Description

surface smoothness

#### Timepoint

3,6,12,18 month

#### Method of measurement

with explorer and visual

### 5

#### Description

colour match

#### Timepoint

3,6,12,18 month

#### Method of measurement

with explorer and visual

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Surfaces were cleaned and dried, then etched for 15 seconds. Excess water was removed leaving the surface slightly moist. embrace Sealant was applied from cusp to cusp without covering marginal ridges and light cured for 20 seconds using a LED light

#### Category

Prevention

### 2

#### Description

Surfaces were cleaned and dried, then etched for 15 seconds. Excess water was removed leaving the surface slightly moist. Helioseal Sealant was applied from cusp to cusp without covering marginal ridges and light cured for 20 seconds using a LED light

#### Category

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Pediatric Department of Tehran Azad University of Dentistry

**Full name of responsible person**

Nazanin Zangeneh

**Street address**

10th neyestan, Pasdaran

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran Azad University of Dentistry

**Full name of responsible person**

Arash Azizi

**Street address**

10th neyestan, Pasdaran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran Azad University of Dentistry

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran Azad University of Dentistry

**Full name of responsible person**

Nazanin Zangeneh

**Position**

pediatric resident of Tehran Azad University of Dentistry

**Other areas of specialty/work****Street address**

10th neyestan, Pasdaran

**City**

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**Postal code****Phone**

+98 21 4421 0303

**Fax****Email**

den\_zangeneh@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran Azad University of Dentistry

**Full name of responsible person**

Nazanin Zangeneh

**Position**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran Azad University of Dentistry

**Full name of responsible person**

Nazanin Zangeneh

**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*