

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 2026

Comparative clinical performance evaluation of different materials in restoration of none carious cervical lesions in patients refer to restorative department of esfahan dentistry university

Protocol summary

Summary

Objective of study is: The comparison between clinical performance index of different materials in restoration of None carious cervical lesions. Design: Not blinded randomized clinical trial Participants and major eligibility criteria: 25 patients with none carious cervical lesions, the patients must have 5 lesions with the depth of 2 mm or more Major exclusion criteria: Carious lesions Setting and conduct: The teeth will clean with rubber cup and pumice before restoring of the teeth. The shade selection done and no preparation and bevel is required. Isolation with cotton rolls and suction will be done and then the teeth randomly will divide into 5 groups. Intervention: In the first group after etching and bonding (Clearfill SE Bond) procedure, the cavity will restore only with Point4 composite. In the second group after etching and bonding (Clearfill SE Bond) cavity will restore only with Gradia flow composite. In the third group cavity will restore with Resin modified glass ionomer Fuji II LC. In the fourth group after use of Dentin conditioner (10% Polyacrylic acid) Conventional glass ionomer (EQUIA FIL), will use to restore cavity. In fifth group at first Vitrebond will use as an intermediate layer and after curing, Point 4 composite will use to cover it (Sandwich technique). Then all of the groups will finish with ultrafine bur and will polish with Sof-Lex Pop On discs. The teeth will be assessed with Modified United States Public Health Service criteria (USPHS) in terms of Retention (main outcome variables), Marginal integrity, Marginal discoloration, Recurrent caries, Surface texture and Anatomic form after 6 months and 12 months, finally the results will be evaluated with statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121925607N1**

Registration date: **2016-04-10, 1395/01/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-10, 1395/01/22

Registrant information

Name

Sepideh Kazemizadeh

Name of organization / entity

Esfahan dentistry school/Esfahan university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Esfahan university of medical science

Expected recruitment start date

2016-03-15, 1394/12/25

Expected recruitment end date

2016-04-29, 1395/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative clinical performance evaluation of different materials in restoration of non-carious cervical lesions in patients referred to restorative department of Esfahan dentistry university

Public title

The effect of different restorative material in the cervical of teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non-carious lesions; depth of lesions 2 mm or more; enamel and dentin involvement without pulpal involvement and mobility of tooth; lesions in buccal surface
Exclusion criteria: Carious lesions; patients with poor oral hygiene; history of bruxism and xerostomia; complicated systemic conditions; severe chronic periodontitis and severe attrition (more than 50% loss of occlusal and incisal)

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan university of medical science

Street address

Esfahan university of medical science, Hezarjarib avenue, Esfahan

City

Esfahan

Postal code

8174673461

Approval date

2015-04-30, 1394/02/10

Ethics committee reference number

ir.mui.rec.1394.3.857

Health conditions studied

1

Description of health condition studied

Non-carious cervical lesions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Retention

Timepoint

6 and 12 Months after intervention

Method of measurement

USPHS Chart

Secondary outcomes

1

Description

Marginal integrity

Timepoint

6 and 12 Months after intervention

Method of measurement

USPHS Chart

2

Description

Marginal Discoloration

Timepoint

6 and 12 Months after intervention

Method of measurement

USPHS Chart

3

Description

Recurrent Caries

Timepoint

6 and 12 Months after intervention

Method of measurement

USPHS Chart

4

Description

Surface Texture

Timepoint

6 and 12 Months after intervention

Method of measurement

USPHS Chart

5

Description

Anatomic Form

Timepoint

6 and 12 Months after intervention

Method of measurement

USPHS Chart

Intervention groups

1

Description

First group:Point 4 Composite

Category

Treatment - Drugs

2

Description

Second group:Gradia flow Composite

Category

Treatment - Drugs

3

Description

Third group:Fuji II LC

Category

Treatment - Drugs

4

Description

Forth group:Equia Fil

Category

Treatment - Drugs

5

Description

Fifth group:Vitre bond+Point 4 Composite

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Professional operative department of Esfahan dentistry school

Full name of responsible person

Dr Farzaneh Shirani(Professor of operative dentistry)

Street address

Esfahan dentistry school, Esfahan university of medical science, Hezarjarib avenue, Esfahan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Esfahan university of medical science

Full name of responsible person

Dr mehdi nematbakhsh(Vice chancellor for research of Esfahan university of medical science)

Street address

Vice chancellor, Esfahan university of medical science,Hezarjarib avenue, Esfahan

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Grant name

Grant code / Reference number

394857

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Esfahan university of medical science

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

Esfahan Dentistry School

Full name of responsible person

Doctor Sepideh Kazemizadeh

Position

Dentist/postgraduate of operative dentistry

Other areas of specialty/work

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Full name of responsible person

Dr Farzaneh Shirani

Position

Profosser of Operative Dentistry

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Full name of responsible person

Doctor Farzaneh Shirani

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Professor of operative dentistry/Professor of dentistry school

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

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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