

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical evaluation of a Low-shrinkage Methacrylate-Based composite compared with a packable composite in posterior restorations

Protocol summary

Summary

The aim of this study is to evaluate the clinical performance of two composites (P60, Kalore) in posterior restorations. In this randomized clinical trial study, fifty restorations are placed in 25 patients. Each patient receives two class I or II restorations. Half of cavity preparations were randomly restored with P60 and the other half with Kalore GC. Patients with poor oral hygiene, parafunctional habits, a known allergy to the substances used in this study, and periodontal diseases were excluded. Informed consent was obtained from each patient. The restorations are evaluated by two independent examiners after one week (baseline), six months and one year according to the modified United States Public Health Service (USPHS) criteria. The evaluated characteristics are: colour match, marginal adaptation, anatomical form, retention, surface texture, post-operative sensitivity, marginal staining and secondary caries. For each of the criteria, a score of Alpha represented the ideal clinical situation, Bravo was clinically acceptable, and Charlie indicated a clinically unacceptable situation. Two examiners, analyst and patients were unaware which composite is used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070528804N1**

Registration date: **2016-07-17, 1395/04/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-17, 1395/04/27

Registrant information

Name

Razieh Hosseinifar

Name of organization / entity

Dental School, Kerman University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2015-07-05, 1394/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of a Low-shrinkage Methacrylate-Based composite compared with a packable composite in posterior restorations

Public title

evaluation of tooth colored restoration materials

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: over 18 years old, stable dentition without periodontal disease, 2 restorations required, vital tooth; exclusion criteria: poor oral hygiene, parafunctional habits, a known allergy to the substances

used in this study, history of existing tooth sensitivity, pregnancy or breast-feeding, chronic use of anti-inflammatory, analgesic, and psychotropic drugs

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study the patients, the researchers and the analyst were unaware of the type of composite, therefore it considers as three blind. Randomization: In order to fill the first cavity, regardless of the type of it (class I or II), between the two composite draw was performed and selected composite was used. Thus the second hole was filled with second composite.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman Univesity of Medical Sciences

Street address

begining of Haftbagh Alavi highway

City

Kerman

Postal code

Approval date

2014-01-05, 1392/10/15

Ethics committee reference number

480/92/l.س

Health conditions studied

1

Description of health condition studied

clinical performance of tooth colored restoration materials

ICD-10 code

K02.1

ICD-10 code description

dentin caries

Primary outcomes

1

Description

retention

Timepoint

one week, 6 months and one year

Method of measurement

visual examination

Secondary outcomes

1

Description

color match

Timepoint

one week, 6 months and one year

Method of measurement

visual examination and photography

2

Description

marginal adaptation

Timepoint

one week, 6 months and one year

Method of measurement

visual and tactile examination with explorer

3

Description

surface roughness

Timepoint

one week, 6 months and one year

Method of measurement

visual and tactile examination with explorer

4

Description

marginal staining

Timepoint

one week, 6 months and one year

Method of measurement

visual examination and photography

5

Description

sensitivity

Timepoint

one week, 6 months and one year

Method of measurement

asking the patient

6

Description

secondary caries

Timepoint

one week, 6 months and one year

Method of measurement

visual and tactile examination with explorer and radiography

7

Description

anatomical form

Timepoint

one week, 6 months and one year

Method of measurement

visual examination

Intervention groups

1

Description

Teeth restoring with tooth colored material Filtek P60 (3M, ESPE, St Paul, USA)

Category

Treatment - Other

2

Description

Teeth restoring with tooth colored material Kalore GC (GC Corporation, Tokyo, Japan)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Dental School

Full name of responsible person

Razieh Hosseinifar

Street address

end of Shafa Ave., Kerman Dental School

City

kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

dr Abbas Pardakhty

Street address

begining of Ebn-e-Sina Ave., Tahmasbabad four-way

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kerman University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Dentistry, Kerman University of Medical Sciences

Full name of responsible person

Hassan Mollahassani

Position

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Other areas of specialty/work

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Web page address**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