

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation the color match of two single shade resin composites; Charisma Diamond ONE and Charisma Topaz ONE in class five restorations and assessment of dentist and patient satisfaction

Protocol summary

Study aim

Evaluation the color match of two single shade resin composites; Charisma Diamond ONE and Charisma Topaz ONE

Design

Superiority clinical trial with control group(Charisma topaz One), with parallel groups, three-blind, simple randomization on 50 sample. For randomization The patient is asked to choose an envelope, among the 50 initial envelopes, for each tooth that represents the type of restoration material.

Settings and conduct

The color of the tooth is recorded once before restoration and then 24 hours after the restoration by a spectrophotometer and three color components a, b and l. Evaluation of the level of satisfaction of the dentist and the patient with the color matching is done using Likert scored criteria The location of the study is the special clinic of the Faculty of Dentistry of Mashhad. It is a three-blind study by blinding the patients, evaluators, and analysts.

Participants/Inclusion and exclusion criteria

Participants must be over 18 years of age; have no visible discoloration on their teeth; and have medium-sized cervical caries in the buccal surface of their teeth. Patients with systemic diseases; severe periodontal diseases; dry mouth; patients with high risk of decay; smoking; patients or people undergoing orthodontic treatment are excluded from the study. Also, teeth with previous restorations or a history of root canal treatment and teeth with periapical lesions will not be evaluated.

Intervention groups

Single shade resin composite; Charisma Diamond ONE

Main outcome variables

The color of tooth is recorded once before restoration and then 24 hours after the restoration by a spectrophotometer and three color components a, b and

l. Evaluation of the level of satisfaction of the dentist and the patient with the color matching is done using Likert scored criteria.

General information

Reason for update

The predicted and realized sample size is 50, which was entered incorrectly

Acronym

IRCT registration information

IRCT registration number: **IRCT20221024056284N1**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **retrospective**

Last update: **2023-07-15, 1402/04/24**

Update count: **1**

Registration date

2023-06-03, 1402/03/13

Registrant information

Name

Atiye Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3871 6272

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

2023-01-21, 1401/11/01

Actual recruitment end date

2023-03-04, 1401/12/13

Trial completion date

2023-03-05, 1401/12/14

Scientific title

Evaluation the color match of two single shade resin composites; Charisma Diamond ONE and Charisma Topaz ONE in class five restorations and assessment of dentist and patient satisfaction

Public title

Evaluation the color match of two single shade resin composites; Charisma Diamond ONE and Charisma Topaz ONE

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Over the age of 18 y/o Do not have a significant color change on their teeth Have medium-sized cervical caries in the buccal surface

Exclusion criteria:

Patients with systemic disease Patients with Xerostomia Patients with high risk of decay Smoker patients Patients with orthodontic treatment Teeth with root canal treatment Teeth with periapical lesion Severe periodontal diseases Teeth with previous restorations

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Tooth with class 5 caries

Actual sample size reached: **50**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Tooth with class 5 caries

Randomization (investigator's opinion)

Randomized

Randomization description

The patient is asked to choose an envelope, among the 50 initial envelopes, for each tooth that represents the type of restoration material.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The samples are randomly divided into two groups. Teeth restoration is done by one person and color

evaluation by two other people. The person who performs the restoration, the patient, the color evaluators of the restoration are blind, and the data analyzer is also blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Dentistry - Mashhad University of Medical Sciences

Street address

Faculty of Dentistry , Vakil Abad Blvd., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1401.129

Health conditions studied**1****Description of health condition studied**

Class 5 dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes**1****Description**

Color on the red-green axis (a)

Timepoint

The color of tooth is measured before the intervention and the color of the restoration is measured 24 hours after the restoration

Method of measurement

Spectrophotometry

2**Description**

Color on the yellow-blue axis (b)

Timepoint

The color of tooth is measured before the intervention and the color of the restoration is measured 24 hours after the restoration

Method of measurement

Spectrophotometry

3

Description

lightness value (L)

Timepoint

The color of tooth is measured before the intervention and the color of the restoration is measured 24 hours after the restoration

Method of measurement

Spectrophotometry

4

Description

Patient satisfaction level

Timepoint

24 hours after restoration

Method of measurement

Evaluation of patients' satisfaction with color matching of the restoration and tooth is done using a 5-point Likert scale.

5

Description

Dentist satisfaction level

Timepoint

24 hours after restoration

Method of measurement

The visual evaluation of the color matching of the restoration and the tooth is done by two trained observers based on the Likert scale.

Secondary outcomes

empty

Intervention groups

1

Description

The use of Charisma Diamond ONE single shade composite from kulzer company in class 5 restorations

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Clinic of Mashhad Faculty of Dentistry

Full name of responsible person

Dr Hamide Mohammadipour

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Faculty of Dentistry , Vakil abad Blvd , Mashhad

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Email

mohammadipourh@mums.ac.ir

Web page address

<https://dentistry.mums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Amir Moeintaghavi

Street address

Faculty of Dentistry , Vakil abad Blvd , Mashhad

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Web page address

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Grant name

Vice-Chancellor's Office for Research of Mashhad university of medical science

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Mohammadipour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamideh Mohammadipour

Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Atiye Mirzaei

Position

student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be published after being unidentifiable and kept confidential.

When the data will become available and for how long

After publishing the results in the form of an article

To whom data/document is available

All researchers in the relevant fields

Under which criteria data/document could be used

Based on the law of the Ministry of Health in connection with clinical trial studies

From where data/document is obtainable

Vice-Chancellor's Office for Research of Mashhad university of medical science

What processes are involved for a request to access data/document

After the approval of the relevant official, the data will be provided to the researcher

Comments