

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Clinical evaluation of the effect of 2% chlorhexidine in dentin treatment procedure on the postoperative sensitivity of posterior composite resin restorations

Protocol summary

Summary

Post operative sensitivity (POS) following composite restorations still remains as a major problem. The aim of this study is clinical evaluation of the effect of 2% chlorhexidine in dentin treatment procedure on the POS of posterior composite resin restorations. 30 patients (aged 20-35 years old) with two posterior teeth with similar caries on both sides of jaw are selected according to the inclusion and exclusion criteria. Patients participate in the study with their consent. After cavity preparation, each of the selected teeth in an individual randomly restore with one of the following methods: tooth in the control group will etch with phosphoric acid 37% (Ultradent) and then restored with dentin bonding system (Single Bond, 3M) and composite (Bisco,3M) according to the manufacturer's instructions. In the other group restoration is similar to the control group but after etching, tooth is wet with chlorhexidine 2% for 60 second. Patients are followed in the intervals of one day, one week, one month and six months. POS will be examined with visual analogue scale method and clinical status of restoration will evaluated with modified USPHS criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104236267N1**
Registration date: **2012-01-10, 1390/10/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-10, 1390/10/20

Registrant information

Name

Hila Hajizadeh

Name of organization / entity

Mashad Dental School, Department of Restorative Dntistry

Country

Iran (Islamic Republic of)

Phone

+98 51 1765 2219

Email address

hajizadehh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-06-22, 1390/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effect of 2% chlorhexidine in dentin treatment procedure on the postoperative sensitivity of posterior composite resin restorations

Public title

Effect of chlorhexidine(CHX) on post operative sensitivity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Having two teeth with similar caries

lesion in each side of the jaw; indication for composite restoration and age 20 to 35 years old. teeth were not restored before. Patient wants tooth color restoration
Exclusion criteria: teeth with restoration; allergy to composite; participation in other test; negative response to vitality test; symptom of irreversible pulpitis and necrosis; pregnancy or other systemic disease and tooth sensitivity due to cervical abrasion

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Mashhad University of Medical Sciences

Street address

Ghorashee building, Daneshgah street,

City

Mashhad

Postal code

Approval date

2011-02-12, 1389/11/23

Ethics committee reference number

89627

Health conditions studied

1

Description of health condition studied

Post operative sensitivity

ICD-10 code

K03.8

ICD-10 code description

Other specified diseases of hard tissues of teeth

2

Description of health condition studied

Clinical evaluation of teeth restoration

ICD-10 code

K03.9

ICD-10 code description

Disease of hard tissues of teeth, unspecified

Primary outcomes

1

Description

Post operative sensitivity

Timepoint

One week, 1 and 6 months after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Clinical evaluation of restoration

Timepoint

One week, 1 & 6 months after intervention

Method of measurement

US Public Health Service (USPHS) Criteria

Intervention groups

1

Description

Restoration with application of chlorhexidine

Category

Prevention

2

Description

restoration with no chlorhexidine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashad Dental School

Full name of responsible person

Street address

City

Mashad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Jalil Tavakol Afshar

Street address

Mashhad University of Medical Sciences, Buali
instittue, Buali squar.

City

Mashhad

Grant name

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

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

Mashad Dental School

Full name of responsible person

Sara Majidinia

Position

Asisstant of dental operative dentistry

Other areas of specialty/work

Street address

Mashad Dental School, Park squar,

City

Mashad

Postal code

Phone

+98 51 1765 2817

Fax

Email

sara_majidinia@yahoo.com;

majidinias881@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashad Dental School

Full name of responsible person

Sara Majidinia

Position

Asisstant of dental operative dentistry

Other areas of specialty/work

Street address

Mashad Dental School, Park squar,

City

Mashad

Postal code

Phone

+98 51 1765 2817

Fax

Email

sara_majidinia@yahoo.com;

majidinias881@mums.ac.ir

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