

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Clinical evaluation of marginal adaptation of three-unit metal ceramic restoration fabricated using conventional impression technique and the new CAD/CAM technology in a randomized clinical trial study

#### Protocol summary

##### Study aim

Clinical evaluation of marginal adaptation of three-unit metal ceramic restoration fabricated using conventional impression technique and the new CAD/CAM technology in a randomized clinical trial study

##### Design

Clinical trial with parallel groups, double-blind, randomized, on 33 patients. Excel software rand function was used for randomization.

##### Settings and conduct

Patients are visited at the dentist's office to assess the outcome. Part of the work is done in the research center laboratory, but the patient does not need to be present. Both the patient and the outcome assessor will be unaware of how the allocation process is done.

##### Participants/Inclusion and exclusion criteria

Periodontal health, Teeth: need restoration, have enough periodontal support, have sufficient length of preparation, have a positive long-term prognosis The patient is willing to participate in our study , Systemic disease Poor oral hygiene Periodontitis, severe gingivitis and high caries activity Obvious signs and symptoms of bruxism or clenching Periodontal surgery required before preparation Second or higher degree of mobility, clinical signs

##### Intervention groups

1. Includes 11 patients in which two basic teeth are examined in each patient. They receive the cobalt chrome three-unit restoration fabricated by the traditional casting method. 2. Includes 11 patients in which two basic teeth are examined in each patient. They receive the cobalt chrome three-unit restoration fabricated by CAD / Milling method from hard metal blocks. 3. Includes 11 patients in which two basic teeth are examined in each patient. They receive the cobalt chrome three-unit restoration fabricated by CAD / Ceramill Sintron method from soft metal blocks.

##### Main outcome variables

The main outcome includes marginal restoration compliance and the secondary consequences include internal and occlusal compliance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160213026538N7**

Registration date: **2022-01-28, 1400/11/08**

Registration timing: **prospective**

Last update: **2022-01-28, 1400/11/08**

Update count: **0**

##### Registration date

2022-01-28, 1400/11/08

##### Registrant information

##### Name

Hedaiat Moradpour

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3729 6910

##### Email address

h.moradpour@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-30, 1400/11/10

##### Expected recruitment end date

2022-05-20, 1401/02/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical evaluation of marginal adaptation of three-unit metal ceramic restoration fabricated using conventional impression technique and the new CAD/CAM technology in a randomized clinical trial study

**Public title**

Clinical evaluation of marginal adaptation

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Periodontal health, plaque index and BOP should be below 20% before prosthetic treatment Abutment teeth require restoration Abutment teeth Have enough periodontal support for three-unit restoration. Abutment Teeth have sufficient length of preparation Abutment teeth have a positive long-term prognosis The patient is willing to participate in our study and sign the consent form

**Exclusion criteria:**

The patient has a systemic disease that affects clinical outcomes The patient is unwilling or unable to maintain adequate oral hygiene The patient has periodontitis, severe gingivitis and high caries activity The patient has obvious signs and symptoms of bruxism or clenching Abutment teeth require periodontal surgery before preparation Abutment teeth have second or higher degree of mobility Abutment teeth have clinical signs

**Age**

From **22 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **33**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A table of random numbers is used for randomization. In Excel software environment, four-digit codes are generated using the RANDBETWEEN command. Each patient is assigned a 4-digit code. If the last digit on the right is 1, 2 or 5, the patient is in the casting group, and if the last digit is 6, 3 or 8, the patient is assigned to the CAD Milling group. And if it is 7, 9 or 4, it is assigned to the CAD Ceramill Sintron group (Number zero is not considered). All codes are Written on papers and are kept in specific envelopes, which are randomly arranged. Registration and evaluation of entrance criteria is done

by the secretary. When all the criteria for entering the study have been reviewed and the patient's information have been recorded, the secretary in charge of conducting the study will give one of these envelopes to the doctor. The doctor will decide on the treatment plan based on the specified code. Random sequencing is performed by a statistical and epidemiological consultant using Excel software. The secretary only cooperates to conduct the study and has no information about the study hypothesis or the group codes. The outcome assessor also has no information on how patients are coded and assigned, but the doctor doing the assignment of intervention is aware of the group codes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double-blinded trail. Patients will not be aware of the process of fabricating restorations and will also not be aware of which study group they are in. Also, the person in charge of evaluating the outcome has no information about how restorations are made. Therefore, both the patient and the outcome assessor will be unaware of how the allocation process is done

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Shahid Beheshti Boulevard - Central Building of Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714869914

**Approval date**

2022-01-24, 1400/11/04

**Ethics committee reference number**

IR.KUMS.REC.1400.739

## Health conditions studied

1

### Description of health condition studied

Marginal mismatch

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

Marginal restoration adaptation

### Timepoint

Before and after veneering

### Method of measurement

1. Parallel bitwing radiograph 2. Probe 3. Silicone replica

## Secondary outcomes

1

### Description

Internal and occlusal adaptation

### Timepoint

Before and after veneering

### Method of measurement

1. Parallel byte wing radiography 2. Probe 3. Silicone replica

## Intervention groups

1

### Description

Intervention group: Traditional casting method

### Category

Prevention

2

### Description

Intervention group: CAD / Milling method from hard metal blocks

### Category

Prevention

3

### Description

Intervention group: CAD / Ceramill Sintron method from soft metal blocks

### Category

Prevention

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Dr. Hedayat Moradpour's dental office

#### Full name of responsible person

Hedaiat Moradpour

#### Street address

Kashani St., Dabirazam Alley, Arshia Building, Unit 11

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6713739988

#### Phone

+98 83 3729 6920

#### Email

hedaiat.moradpoor@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Farid Najafi

#### Street address

Vice Chancellor for Research Kermanshah University of Medical Sciences, Central building, Shahid Beheshti Boulevard, Kermanshah

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Phone

+98 83 3729 6591

#### Email

fnajafi@kums.ac.ir

### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Vahid Vahedi

**Position**

Under graduated Student of Dentistry

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

The school of Dentistry, shariati Street, Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713954658

**Phone**

+98 83 3724 8531

**Email**

v.vahedids@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Hedaiat Moradpour

**Position**

Prosthodontics Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Department of Prosthodontics, The school of  
Dentistry, Kermanshah University of Medical Sciences  
, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713954658

**Phone**

+98 83 3729 6910

**Fax****Email**

h.moradpour@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Vahid Vahedi

**Position**

Under graduated Student of Dentistry

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

The school of Dentistry, shariati Street, Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713954658

**Phone**

+98 83 3724 8531

**Email**

v.vahedids@gmail.com

## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available