

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A comparative evaluation of clinical outcome of fully digital and conventional workflow in three-unit implant supported restorations: a clinical trial

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the accuracy of impressions, the fitness and passivity of the frameworks, the occlusions, cost and time for building restorations in digital workflow and conventional workflow

##### Design

10 patients, cross over study

##### Settings and conduct

The patients who received two bone level implants (Dentium company) in faculty of dentistry of Tehran university of medical science or in implants research center were added in the study. they implants are in the posterior of the mandible and they need 3 units restorations after healing time. the accuracy of the impressions, the passivity and fitness of frameworks, the occlusion, aesthetic, time and cost of two restorations are evaluated.

##### Participants/Inclusion and exclusion criteria

Patients who received two implants (dentium company) and need 3 units restorations, the depth of implants lower than 5 mm from gingiva, the degree between two implants lower than 10, the inter occlusal space lower than 15 mm.

##### Intervention groups

Conventional impression, Conventional framework, Digital impression, Digital framework

##### Main outcome variables

Accuracy of impressions, passivity, accuracy, aesthetic, occlusion, cost, time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191009045041N1**  
Registration date: **2019-12-16, 1398/09/25**

Registration timing: **prospective**

Last update: **2019-12-16, 1398/09/25**

Update count: **0**

##### Registration date

2019-12-16, 1398/09/25

##### Registrant information

###### Name

Ali Mahmoud Hashemi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2645 5649

###### Email address

a-mahmoudhashemi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-21, 1398/09/30

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative evaluation of clinical outcome of fully digital and conventional workflow in three-unit implant supported restorations: a clinical trial

##### Public title

An evaluation of outcome of two workflow in multi unit

implant supported restoration

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients received 2 bone level implants (dentium company) and need 3 units restorations Implants depth lower than 5 mm from gingiva The degree between two implants are lower than 10

### Exclusion criteria:

Patients received 1 bone level implants (dentium company) and need 1 unit restoration Implants depth more than 5 mm from gingiva The degree between two implants are more than 10

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 10

More than 1 sample in each individual

Number of samples in each individual: 2

Two restorations for all patients

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

For all patients two restorations are built and patients received the better restoration and the other will give them for free.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Science

##### Street address

No. 1, Porsina St., Qods St., Enghelab Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1467664961

## Approval date

2019-12-07, 1398/09/16

## Ethics committee reference number

IR.TUMS.VCR.REC.1398.673

## Health conditions studied

### 1

#### Description of health condition studied

Implant supported restorations

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

accuracy of impressions ( changes in x,y,z axis)

#### Timepoint

after impression

#### Method of measurement

best fit algorithm

## Secondary outcomes

### 1

#### Description

fitness

#### Timepoint

after framework

#### Method of measurement

radiography

### 2

#### Description

passivity

#### Timepoint

after framework

#### Method of measurement

auto cad

### 3

#### Description

occlusion

#### Timepoint

after restoration

#### Method of measurement

auto cad

### 4

#### Description

aesthetic

#### Timepoint

after restoration

#### Method of measurement

VAS

## 5

### **Description**

time

### **Timepoint**

whole time

### **Method of measurement**

study

## 6

### **Description**

cost

### **Timepoint**

whole cost

### **Method of measurement**

study

## **Intervention groups**

### 1

#### **Description**

Intervention group: digital impression, seating scan body and then making impression with intraoral scanner in one session.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: digital framework, milling the restorations with cad cam by private laboratory.

#### **Category**

Treatment - Other

### 3

#### **Description**

Control group: conventional impression, with special tray and poly-vinyl siloxane in one session.

#### **Category**

Treatment - Other

### 4

#### **Description**

Control group: conventional framework, chrome cobalt casting for making frameworks by private laboratory.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Faculty of dentistry, Tehran university of medical science

##### **Full name of responsible person**

Mr Reza Saboohi

#### **Street address**

North kargar Ave

#### **City**

Tehran

#### **Province**

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#### **Postal code**

1439955991

#### **Phone**

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#### **Email**

dentistry@tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr Marzieh Alikhasi (Vice chancellor, Dentistry faculty)

##### **Street address**

North kargar Ave

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##### **Email**

dentistry@tums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Ali Mahmoud Hashemi

##### **Position**

PHD Candidate  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Marzieh Alikhasi  
**Position**  
Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**

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**Email**  
ali.mh.qq@gamil.com

## 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

Yes - There is a plan to make this available

### Title and more details about the data/document

All

### When the data will become available and for how long

After finish

### To whom data/document is available

All

### Under which criteria data/document could be used

Clinical cares

### From where data/document is obtainable

Dentistry faculty

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

Form filling

### Comments