

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)

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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

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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)

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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact

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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

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