

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of Intraoral Ultrasonography Accuracy Compared to Gold Standard Method in Gingival Thickness Assessment on Candidates for Crown Lengthening Surgery

Protocol summary

Study aim

Main Objective : Comparison between ultrasonography and gold standard method in gingival thickness measurement on patients scheduled for crown lengthening.

Design

Study type : Diagnostic clinical trial Gingival thickness will be measured in 34 patients (male & female), and in every patient 40 sites will be measured at the midbuccal of all anterior and premolar teeth in both upper and lower jaw (in each tooth, two sites in 2 & 4 millimeters from free gingival level).

Settings and conduct

All measurements will take place at a private radiologic practice. An ultrasonography (E-CUBE 7,ALPINION) intraoral probe (2 Cm length,12 MHz) will be used to measure thickness on specified locations. The probe will be placed vertically on both tooth and gingiva; measured values will be recorded. 2% lidocaine infiltration will be done and using a size 25 endodontic spreader (Mani, 25 mm,2% convergence) the same sites will be measured as so : The spreader will be inserted in soft tissue until it contacts the hard tissue and then the rubber will be placed on the gingival surface , the inserted length will be measured with a digital caliper. Recorded values will be compared and analyzed.

Participants/Inclusion and exclusion criteria

Patients scheduled for crown lengthening with healthy periodontium. Patients with inflamed gingiva or pregnant Patients or those who take any medication that would cause gingival hyperplasia will be excluded from the study due to measurement bias.

Intervention groups

Intervention group : In this study gingival thickness on every patient will be measured with ultrasonography and then with gold standard method. There are no other intervention groups.

Main outcome variables

Gingival thickness determination in 2 & 4 millimeters from free gingival level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211229053566N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Mohammad Parham Ghomashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4421 7260

Email address

m.parham.gh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Intraoral Ultrasonography Accuracy Compared to Gold Standard Method in Gingival Thickness Assessment on Candidates for Crown Lengthening Surgery

Public title

Evaluation of Intraoral Ultrasonography Accuracy Compared to Gold Standard Method in Gingival Thickness Assessment on Candidates for Crown Lengthening Surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Normal and healthy periodontium Non smokers All anterior teeth and premolars should present in both maxilla and mandible Patient must not be pregnant Patient must not take any medication that would cause gingival hyperplasia

Exclusion criteria:**Age**

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Evin ,

Shahid chamran highway

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2021-12-14, 1400/09/23

Ethics committee reference number

IR.SBMU.DRC.REC.1400.138

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

Gingival Thickness

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mid buccal gingival thickness of premolars and anterior teeth in upper and lower jaw

Timepoint

One time measurement

Method of measurement

Both sounding (gold standard) and intraoral ultrasonography technique

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Comparison between ultrasonography and gold standard method in gingival thickness measurement of crown lengthening candidates

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr Safi's Radiology Clinic

Full name of responsible person

Yaser Safi

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No.203, Mollasadra St, Vanak Square

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Tehran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza zali
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Shahid Beheshti Dental School, Daneshjoo Blvd, Evin ,
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Email
info@sbmu.ac.ir
Web page address
http://dentistry.sbm.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid beheshti dental school

Proportion provided by this source

1

Public or private sector

Private

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Alizad Rahvar
Position

Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Email

m.parham.gh@gmail.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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All information will be available in a form that the patients remain unknown.

When the data will become available and for how long

Information will be available in 2023

To whom data/document is available

All healthcare personnel

Under which criteria data/document could be used

There are no conditions

From where data/document is obtainable

Shahid Beheshti Dental School Tel : +98 21 2242 1811

Email :info@sbmu.ac.ir Radiology department

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

Send a written request

Comments