Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Email
info@sbmu.ac.ir
Web page address
http://dentistry.sbmu.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
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Person responsible for updating data

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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
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