

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical Trial and Hystomorphometric Comparison of Tissue Reaction to Vicryl and Silk Sutures in Patients required Clinical Crown Lengthening

Protocol summary

Summary

Aim: The aim of this clinical trial is clinical & histological comparison of gingival tissue reaction to vicryl and silk sutures. Study design: Randomized, double blind, no placebo, one-centered. Population: Patients aged 20-40 years, both male and female. Inclusion criteria: Absence of systemic disease; patients required crown lengthening in maxillary premolar or molar teeth. Exclusion criteria: Systemic disease; smoking; receiving any type of local and systemic drugs which produced inflammation in gingival tissue or gingival inflammation in surgical site; patients who were received periodontal surgical treatment or antibiotic during past six months; pregnant women and allergy to silk or vicryl products. Sample size: Thirty-two samples in two groups; each containing 16 samples. Interventions: Suturing in the mesial and distal site of maxillary premolar & molar teeth and then removing gingival tissues containing suture materials for histological examination. Intervention duration: One week. Primary Result: Gingival index, the severity of presence acute & chronic inflammatory cells.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061612487N6**

Registration date: **2014-11-18, 1393/08/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-18, 1393/08/27

Registrant information

Name

Shirin Amini

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-02-12, 1391/11/24

Expected recruitment end date

2013-05-26, 1392/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial and Hystomorphometric Comparison of Tissue Reaction to Vicryl and Silk Sutures in Patients required Clinical Crown Lengthening

Public title

Comparison of Tissue Reaction to two Suture Material

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Absence of systemic disease; patients required crown lengthening in maxillary premolar or molar teeth. Exclusion criteria: Systemic disease; smoking; receiving any type of local and systemic drugs which produced inflammation in gingival tissue or gingival inflammation in surgical site; patients who were received periodontal surgical treatment or antibiotic

during past six months; pregnant women and allergy to silk or vicryl products; Samples with insufficient length & depth for counting of acute & chronic inflammatory cells

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo
Used

Assignment
Parallel

Other design features
Randomization: In each patient, the mesial and distal sites of the selected tooth were sutured randomly via throwing the coin by one of the suture materials.
Blindness: Histological investigation was carried out by another examiner who was blind to the selected suture for each sample.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Khorasgan Branch, Islamic Azad University

Street address

Khorasgan Branch, Islamic Azad University, University Boulevard, Arghavaniyeh street, Eastern Jey Street, Isfahan, Iran

City

Isfahan

Postal code

81595158

Approval date

2012-11-11, 1391/08/21

Ethics committee reference number

07859/D/910820

Health conditions studied

1

Description of health condition studied

Foreign body reaction

ICD-10 code

K06.9

ICD-10 code description

Disorder of gingiva and edentulous alveolar ridge, unspecified

Primary outcomes

1

Description

clinical Inflammation of the gingiva

Timepoint

Pretreatment and one week after the treatment

Method of measurement

Gingival index Loe and Sillness

2

Description

Histologic inflammation of the gingiva

Timepoint

Pretreatment and one week after the treatment

Method of measurement

Inflammatory cell count in histologic samples

Secondary outcomes

empty

Intervention groups

1

Description

Applying silk suture (Supa Medical Device, Tehran, Iran)

Category

Diagnosis

2

Description

Applying vicryl suture (Supa Medical Device, Tehran, Iran)

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontology Department, Dental School, Khorasgan Branch, Islamic Azad University

Full name of responsible person

Dr Shirin Amini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice- Chancellor of Islamic Azad University
Khorasgan Branch

Full name of responsible person

Dr Vahid Esfahanian

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Dental School, Khorasgan Branch, Islamic Azad
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City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice- Chancellor of Islamic Azad University
Khorasgan Branch

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental School, Khorasgan Branch, Islamic Azad
University(Isfahan)

Full name of responsible person

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Position

Assistant Professor/ DDS, MSc

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty