

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

+The effect of Vicryl plus suture material on the accumulation of streptococcus mutans and staphylococcus aureus microorganisms on adjacent silk sutures

Protocol summary

Study aim

comparison of the effect of Vicryl plus suture material on the accumulation of streptococcus mutans and staphylococcus aureus microorganisms on adjacent silk sutures with different distances

Design

clinical trial with control group; four parallel group in 20 patients; double blind; Non randomized

Settings and conduct

surgical area is randomly divided into four sites, which one vicryl plus suture and three silk sutures at distance of three, six and nine millimeters of vicryl plus will be placed in it. One week after the surgery, the sutures will be separated and placed in a BHI transfer suspension and transmitted to the microbiological laboratory within twelve hours. Then microorganisms will be cultivated to the specific culture medium of each bacteria from the fluid transfer medium. After culture on the media and placing the culture plate in an incubator at 37 ° C for twenty-four hours, the growth of the bacteria will be checked and the number of colonies (CFU units) will be counted

Participants/Inclusion and exclusion criteria

patients who indicated implant surgery of two adjacent implants, constitute the statistical population of the study. patients with periodontal disease, systemic diseases, or taking other medicines will be excluded from the study

Intervention groups

First intervention group: Use silk suture at a distance of nine millimeters of vicryl plus suture Second intervention group: Use silk suture at a distance of six millimeters of vicryl plus suture Third intervention group: Use silk suture at a distance of three millimeters of vicryl plus suture Control group: use of Vicryl plus suture that is multi-strand and contains Triclosan as an antimicrobial material

Main outcome variables

accumulation of bacteria on surgical sutures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180617040117N2**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Ardavan Etemadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

a-etemadi@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-12, 1397/11/23

Expected recruitment end date

2019-03-14, 1397/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
+The effect of Vicryl plus suture material on the accumulation of streptococcus mutans and staphylococcus aureus microorganisms on adjacent silk sutures

Public title
Accumulation of oral microorganisms around the suture materials in implant surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All patients who have indication for implant surgery in at least two adjacent implant sites
Exclusion criteria:
to have periodontal diseases to have systemic diseases to take other medicines

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **4**
every patient has four suture materials in his mouth as sample

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
After implantation, the surgeon uses four sutures with similar sequences in all patients and one week after surgery, sutures will be delivered to the microbiologist as numerical codes so microbiologist an patient don't know the type of sutures

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of faculty of Dentistry of Islamic Azad University
Street address
Pasdaran Ave, 10th Neyestan , no 4
City
Tehran
Province
Tehran
Postal code
1946853314

Approval date
2018-05-27, 1397/03/06

Ethics committee reference number
IR.IAU.DENTAL.REC.1397.008

Health conditions studied

1

Description of health condition studied
surgical site infection around surgical suture materials

ICD-10 code
A48.8

ICD-10 code description
Other specified bacterial diseases

Primary outcomes

1

Description
accumulation of bacteria on surgical sutures

Timepoint
counting colony forming units after bacterial culture on culture medium

Method of measurement
counts of colonies with naked eye

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: Use silk suture at a distance of nine millimeters of vicryl plus suture

Category
Prevention

2

Description
Intervention group: Use silk suture at a distance of six millimeters of vicryl plus suture

Category

Prevention

3

Description

Intervention group: Use silk suture at a distance of three millimeters of vicryl plus suture

Category

Prevention

4

Description

Control group: use of Vicryl plus suture that is multi-strand and contains Triclosan as an antimicrobial material

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

private office of Dr.ardavan Etemadi

Full name of responsible person

Ardavan Etemadi

Street address

No.12 , Narenjestan7 Ave, Farmaniye Town

City

Tehran

Province

Tehran

Postal code

1957944931

Phone

+98 21 2611 2096

Email

a-etemadi@farabi.tums.as.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nima nadafpoor

Street address

No. 4, Neyestan 10, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2256 4570

Email

n_nadaf@dentaliau.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Ardavan Etemadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No.12 , Narenjestan7 Ave , Farmaniyeh

City

Tehran

Province

Tehran

Postal code

1957944931

Phone

+98 21 2611 2096

Email

a-etemadi@farabi.tums.as.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ardavan Etemadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No.12 , Narenjestan7 Ave , Farmaniyeh

City

Tehran
Province
Tehran
Postal code
1957944931
Phone
+98 21 2611 2096
Email
a-etemadi@farabi.tums.as.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ardavan Etemadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No.12 , Narenjestan7 Ave , Farmaniyeh
City
Tehran

Province
Tehran
Postal code
1957944931
Phone
+98 21 2611 2096
Email
a-etemadi@farabi.tums.as.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information with respect to the subject

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available