

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of Vicryl plus suture material on the accumulation of Enterococcus and E.coli microorganisms on adjacent silk sutures

Protocol summary

Study aim

comparison of the effect of Vicryl plus suture material on the accumulation of Enterococcus and E.coli microorganisms on adjacent silk sutures with different distances

Design

clinical trial with control group; four parallel group in 20 patient; double blind; 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 nine millimeters of vicryl plus suture Third intervention group: Use silk suture at a distance of nine 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: **IRCT20180714040460N3**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Nima Nadafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

n_nadaf@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-02-04, 1397/11/15

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 Enterococcus and E.coli 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**

very 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 central organization of Islamic Azad university

Street address

No. 4, Neyestan 10, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.007

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.Nima Naddaf Pour

Full name of responsible person
Nima Naddaf Pour

Street address
Unit.24 , No.38 , Juy pa alley , Sarv cross , Paknejad blvd , Saadat Aabad town

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Email
n_nadaf@dentaliau.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ardavan Etemadi

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No. 4, Neyestan 10, Pasdaran Ave

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+98 21 2256 4570

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a-etemadi@farabi.tums.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
Nima Nadafpour

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Nima Nadafpour
Position
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Latest degree
Specialist
Other areas of specialty/work
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City
Tehran
Province

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