

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effect of four suture materials on the accumulation of Enterococcus and E.coli microorganisms in patients undergoing dental implant surgery

Protocol summary

Study aim

comparison of the effect of Vicryl Plus, Vicryl, Silk and Nylon sutures on the accumulation of Enterococcus and E.coli microorganisms in patients undergoing Implant Surgery

Design

randomized clinical trial; no control group; single blind

Settings and conduct

surgical area (including the space required to place two adjacent implants) is randomly divided into four sites, and each suture materials including vicryl, vicryl plus, silk and Nylon will be placed in each surgical site at a distance of three millimeters from the adjacent suture. One week after the patient's surgery, the sutures will be separated and placed in a brain heart infusion (BHI) transfer suspension, which all aerobic and anaerobic microorganisms can grow, 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 by a sterilized loop. 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 colony forming units (CFU) will be counted. The mean and standard deviation of the CFU of each suture for each microorganism will be calculated by the kruskal-wallis test, and also between the two sutures will be compared with the Mn-Yo-Whitney test.

Participants/Inclusion and exclusion criteria

Enterococcus and E.coli microorganisms on sutures of 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

Use of various suture materials in the surgical sites in all patients

Main outcome variables

accumulation of bacteria on surgical sutures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180617040117N1**

Registration date: **2018-10-31, 1397/08/09**

Registration timing: **prospective**

Last update: **2018-10-31, 1397/08/09**

Update count: **0**

Registration date

2018-10-31, 1397/08/09

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

2018-11-03, 1397/08/12

Expected recruitment end date

2018-12-03, 1397/09/12

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of four suture materials on the accumulation of Enterococcus and E.coli microorganisms in patients undergoing dental implant surgery

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:
The patient should not have any periodontal diseases
The patient should not have any systemic diseases
The patient should not take any other medicines

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- 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)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
After implantation, the surgeon uses four types of suture materials with random sequences and one week after surgery, sutures will be delivered to the microbiologist as numerical codes so microbiologist doesn't know the type of sutures.

Placebo
Not used

Assignment
Single

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

2018-10-13, 1397/07/21

Ethics committee reference number

IR.IAU.DENTAL.REC.1397/31

Health conditions studied

1

Description of health condition studied

surgical site infection

ICD-10 code

ICD-10 code description

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: The same intervention is applied to all patients, and the intervention involves the use of four different types of suture 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

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

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

Islamic Azad University

Full name of responsible person

Ardavan Etemadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Person responsible for updating data

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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