Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the Bacterial Species and the Mean Number of Bacterial Colonies on Vicryl and Antibacterial Vicryl Sutures Used In Mandibular Third Molar Surgery

Protocol summary

Study aim

this study aims to determine the efficiency of antibacterial vicryl suture in comparison with vicryl suture in the reduction of bacterial colony count and species after surgical extraction of mandibular wisdom teeth.

Design

a double-blinded clinical trial, parallel-group design of 27 self-control participants enrolled between May and July 2019

Settings and conduct

27 patients selected between May and July 2019 among whom in the dentistry faculty of Isfahan university of medical sciences, Isfahan, Iran. After achieving local anesthesia by lidocaine 2% with epinephrine1:80000, a mucoperiosteal flap is elevated and the wisdom tooth is extracted. After that, two interrupted vicryl and antibacterial vicryl sutures are randomly placed in the mesial and distal part of the flap. Location of each suture for each patient is mentioned in patient's form (i.e. "1M" means vicryl suture in mesial and "2D" means antibacterial vicryl suture in distal) After 1 week, sutures are removed and sent to the microbiological laboratory in less than 1 hour, while protected in saline. this study of a double-blinded one in which none of the patients, surgeon, and microbiological technician were aware of the exact location of vicryl and antibacterial vicryl sutures.

Participants/Inclusion and exclusion criteria

having mandibular third molar indicated for surgery is the inclusion criteria and any confounding factor for bacterial count and species would be the exclusion criteria.

Intervention groups

After the surgical extraction of the third molar tooth, two interrupted vicryl and antibacterial vicryl sutures are randomly placed in the mesial and distal part of the flap. After 1 week, sutures are removed and sent to the microbiological laboratory. patients are self-control in this study.

Main outcome variables

type of suture material; predominant bacterial species; count of bacterial colonies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131205015665N3**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Milad Etemadi-Shalamzari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1391 3237

Email address

etemadi@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

2019-05-26, 1398/03/05

Actual recruitment end date

2019-07-11, 1398/04/20

Trial completion date

2019-07-11, 1398/04/20

Scientific title

Evaluation of the Bacterial Species and the Mean Number of Bacterial Colonies on Vicryl and Antibacterial Vicryl Sutures Used In Mandibular Third Molar Surgery

Public title

Evaluation of Antibacterial Suture Efficacy on Reduction of Bacterial Adhesion in Impacted Lower Third Molar Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

having type A mesioangular mandibular third molar indicated for surgical removal having appropriate radiographic imaging age between 18-30 absence of obvious infection and/or extensive caries lesion in the oral cavity

Exclusion criteria:

systemic health problems systemic or oral medication affecting normal oral microbial flora and colonization smoking and drug addiction alcohol addiction presence of intraoral inflammation before the surgery pregnancy and lactation known or suspected allergy to suture and other materials using in this study presence of removable prosthesis in the oral cavity loss of sutures before suture removal appointment presence of infection after surgery or any other situation with the need for antibiotic therapy

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

one suture will be placed in the distal and the other in the mesial part of the flap which one of them is vicryl (control) and the other is antibacterial vicryl (case)suture.

Actual sample size reached: **27**

More than 1 sample in each individual

Actual sample size in each individual: **2**

one suture was placed in the distal and the other in the mesial part of the flap which one of them was vicryl (control) and the other was antibacterial vicryl (case)suture.

Randomization (investigator's opinion)

Randomized

Randomization description

pseudorandomization will be done in this study. after considering an ID for each patient number from 1 to 27, in patients with an odd ID number, vicryl suture is placed in the mesial part and antibacterial vicryl suture in the distal part of the flap. in patients with an even ID number, the antibacterial suture is placed in the mesial part of the flap, while the vicryl suture is placed in the distal part.

Blinding (investigator's opinion)

Double blinded

Blinding description

for blinding the participants: they will not be aware of the exact location of the vicryl and vicryl plus sutures in the mesial and distal part of the flap. for blinding the surgeon: both violet-colored suture materials will be peeled open out of the sight of the surgeon and then given o him for placing the sutures in the mesial and distal part of the flap. for blinding the technician of the microbiological laboratory: tubes containing the suture materials, will be coded as (1) for vicryl and (2) for vicryl plus .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan university of medical sciences

Street address

oral and maxillofacial surgery department, dentistry faculty, Isfahan university of medical sciences,Hezar-jerib st., Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

73461-81746

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.038

Health conditions studied

1

Description of health condition studied
comparison of mean number of bacterial colonies and predominant species on antibacterial vicryl and vicryl sutures
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
mean number of bacterial colonies (cfu/ml) on vicryl and antibacterial vicryl suture materials
Timepoint
1 week after surgery
Method of measurement
calculation of mean number of bacterial colonies grown in blood agar culture medium

2

Description
determining the predominant species
Timepoint
1 week after surgery
Method of measurement
gram coloring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 27 patients selected between May and July 2019 and January 2019 among patients in the dentistry faculty of Isfahan university of medical sciences, Isfahan, Iran. After achieving local anesthesia by lidocaine 2% with epinephrine1:80000, a mucoperiosteal flap is elevated and the third molar tooth is extracted. After that, an interrupted vicryl suture is randomly placed in the mesial or distal part of the flap. Location of each suture for each patient is mentioned in patient's form (i.e. "1M" means vicryl suture in mesial and "2D" means antibacterial vicryl suture in distal) After 1 week, the suture is removed and sent to the microbiological laboratory in less than 1 hour, while protected in saline. the suture is transferred to the thioglycolate culture media and processed within 1 hour. For each sample, a one-tenth diluted solution with 0.9% NaCl is made and 100µL of it was used on blood agar culture medium and then Incubation is done in 37 degrees of temperature for 2-4 days. Gram coloring is done and cellular morphology is assessed under an optical microscope.
Category
Treatment - Other

2

Description
Intervention group 2: 27 patients selected between May and July 2019 and January 2019 among patients in the dentistry faculty of Isfahan university of medical sciences, Isfahan, Iran. After achieving local anesthesia by lidocaine 2% with epinephrine1:80000, a mucoperiosteal flap is elevated and the third molar tooth is extracted. After that, an interrupted antibacterial vicryl suture is randomly placed in the mesial or distal part of the flap. Location of each suture for each patient is mentioned in patient's form (i.e. "1M" means vicryl suture in mesial and "2D" means antibacterial vicryl suture in distal) After 1 week, the suture is removed and sent to the microbiological laboratory in less than 1 hour, while protected in saline. the suture is transferred to the thioglycolate culture media and processed within 1 hour. For each sample, a one-tenth diluted solution with 0.9% NaCl is made and 100µL of it was used on blood agar culture medium and then Incubation is done in 37 degrees of temperature for 2-4 days. Gram coloring is done and cellular morphology is assessed under an optical microscope.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry faculty of Isfahan University of Medical Sciences
Full name of responsible person
Milad Etemadi Shalamzari
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Department of oral and maxillofacial surgery, dentistry faculty, Isfahan university of medical sciences, Hezar--jerib st., Isfahan, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address

Vice-chancellor in research affairs, Isfahan university of medical sciences, Hezar-jerib st., Isfahan, Iran.

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Phone
+98 31 3668 8138

Email
research@mui.ac.ir

Web page address
https://research.mui.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan University of Medical Sciences

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
Esfahan University of Medical Sciences

Full name of responsible person
Milad Etemadi Shalamzari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Oral and Maxillofacial Surgery

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Position
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Latest degree
Specialist

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Dentistry

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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 further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

study protocol;

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

no other condition

From where data/document is obtainable

sending request email to "sameenrah@gmail.com"

What processes are involved for a request to access data/document

10 days after sending a request to "sameenrah@gmail.com", data will be sent.

Comments