

# 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 epinephrine 1:80000, 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**

Isfahan

**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 epinephrine 1:80000, 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 epinephrine 1:80000, 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

#### **Street address**

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#### **Postal code**

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etemadi@dnt.mui.ac.ir

## **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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**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

**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**

Dentistry

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## Person responsible for updating data

**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**

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**