

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of effectiveness of Simple continuous suture and Reciprocal continuous suture in healing intraoral incisions: double blind, split mouth randomized clinical trial

#### Protocol summary

##### Study aim

The main purpose of this study is to compare the effectiveness of Simple continuous suture and Reciprocal continuous suture in intraoral incisions healing.

##### Design

A randomized controlled, double blind, split mouth clinical trial. For randomization Balanced Block Randomization method is done.

##### Settings and conduct

This study is about the effectiveness of two types of suturing techniques that are performed in the Faculty of Dentistry, University of Tehran. 14 patients with complete or partial edentulous will be candidate for implant surgery. Sutures will be applied randomly on each side.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. People with complete or partial edentulous on both sides of the Maxillary arch who are candidates for implant surgery. 2. Healthy people (without systemic diseases) 3. People who do not smoke 4. Women who are not during pregnancy 5. Women who are not during breastfeeding 6. People who visit for follow-up sessions 7. People who do not need bone grafts for implant surgery Exclusion criteria: 1. Patients with systemic disease 2. Pregnant women 3. Smokers 4. Women who are breastfeeding 5. People who need bone grafts for implant surgery 6. People who do not seek follow-up sessions

##### Intervention groups

After implant placement in both sides of Maxillary arch, with Balanced Block Randomization technique decides which suture technique should be performed on each side of the Maxilla. In intervention group Reciprocal continuous suture and in control group Simple continuous suture will be perform.

##### Main outcome variables

Dehiscence, Suture loosening, Inflammation, Suture

technique

#### General information

##### Reason for update

Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20211121053131N1**

Registration date: **2022-01-18, 1400/10/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-18, 1400/10/28**

Update count: **0**

##### Registration date

2022-01-18, 1400/10/28

##### Registrant information

###### Name

Houra Astaneh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2284 9948

###### Email address

huas74@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-02, 1400/10/12

##### Expected recruitment end date

2022-03-03, 1400/12/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of effectiveness of Simple continuous suture and Reciprocal continuous suture in healing intraoral incisions: double blind, split mouth randomized clinical trial

**Public title**  
Comparison of effectiveness of two types of suture during intraoral incisions healing

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Healthy people(without systemic diseases) People who do not smoke Women who are not during pregnancy Women who are not during breastfeeding People who visit for follow-up sessions People who do not need bone grafts for implant surgery  
**Exclusion criteria:**  
Patients with systemic disease Smokers Pregnant women Women who are breastfeeding Patients who need bone graft for implant surgery Patients who do not seek follow-up sessions

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **14**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
For each person, each side of the maxillary arch is considered as a sample. We randomly perform Reciprocal continuous suture on one side and Simple continuous suture on the other side.

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study there are 4 randomized interventions. Right side first or left side, and each one is first can be sutured either with Reciprocal continuous suture or Simple continuous suture. 1) Right side first, suturing with Reciprocal continuous technique. 2) Right side first, suturing with Simple continuous technique. 3) Left side first, suturing with Reciprocal continuous technique. 4) Left side first, suturing with Simple continuous technique. There are 14 patients in this study. In this method we write down these 4 interventions in 4 similar sealed envelopes (there is 1 intervention in each envelope). For each 4 patients we have 4 envelopes, for first patient we choose one envelope randomly. For second patient we choose one envelope from 3 remaining envelopes and so

on until the last patient. In the end this process will be done 3 times for 12 patients. For 2 remaining patients we have 2 new envelopes that are sealed and similar. In each 2 envelopes we write one of the interventions, it means that for each intervention we have a separate envelope. This method is called Balanced Block Randomization.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients do not know which type of suture is performed on which side of the maxilla. With Balanced Block Randomization method surgeon will decide to do which suture technique on each side. Also impact assessor does not know which type of suture is performed on which side of the maxilla because he evaluates the photographs that is taken after suture removal.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran university of medical sciences international campus school of dentistry, Mahan St., Zam Zam St., Navab Highway, Tehran, Iran

**City**

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**Province**

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**Postal code**

1417653761

**Approval date**

2020-07-29, 1399/05/08

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1399.057

**Health conditions studied**

**1**

**Description of health condition studied**

This study evaluates the effectiveness of a new suturing technique that has been invented by researcher. This technique name is Reciprocal continuous suture which is a type of continuous suture.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

Dehiscence: Pathologic process consisting of a partial or complete disruption of the layers of a surgical wound

#### Timepoint

7 days and 14 days after surgery

#### Method of measurement

Intraoral measuring instruments (graded bisturi handle - mm)

### 2

#### Description

Inflammation: A pathological process characterized by injury or destruction of tissues caused by a variety of cytologic and chemical reactions. It is usually manifested by typical signs of pain, heat, redness, swelling, and loss of function.

#### Timepoint

7 days and 14 days after surgery

#### Method of measurement

Pale pink: without inflammation, change in color from normal pale pink: inflammation

### 3

#### Description

Suturing loosening

#### Timepoint

7 days after surgery

#### Method of measurement

Intraoral measuring instruments (graded bisturi handle - mm)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The side of Maxilla that receives Reciprocal continuous suture is intervention group. First, each side of the Maxilla is anesthetized with approximately 2 carpules of Lidocaine anesthetic and infiltration technique. With a razor number 15 (Morris Company), the Crestal incision is done, envelope flap is prepared and the flap is retracted mucoperioceally. The most posterior region of the maxilla where the implant is placed is first maxillary molar. One implant system is used for all patients and all implants are placed with 2 stage technique. After implant placement, one side of the maxilla is sutured with Simple continuous suture technique (control group) and the opposite side is sutured with the Reciprocal continuous suture technique (intervention group). The suturing process on each side is completely random (Balanced Block Randomization method) and it means that the surgeon didn't apply his

personal opinion for suturing (which side first and which suturing technique first). The point where the needle enters the tissue is far 3 mm from the edge of the wound. The surgical site is sutured with 0.3 Vikril absorbable (slowly absorb) suture (brand name: SUPABON made in Iran / SUPA company) with a 19 mm reverse cutting needle and a 3.8 gauge. Both side sutures will be remove 7 days after surgery. On surgery day, 7 days and 14 days after surgery intraoral photograph is taken. In the end intraoral photographs will be evaluate by impact assessor with AutoCAD software.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: The side of Maxilla that receives Simple continuous suture is control group. First, each side of the Maxilla is anesthetized with approximately 2 carpules of Lidocaine anesthetic and infiltration technique. With a razor number 15 (Morris Company), the Crestal incision is done, envelope flap is prepared and the flap is retracted mucoperioceally. The most posterior region of the maxilla where the implant is placed is first maxillary molar. One implant system is used for all patients and all implants are placed with 2 stage technique. After implant placement, one side of the maxilla is sutured with Simple continuous suture technique (control group) and the opposite side is sutured with the Reciprocal continuous suture technique (intervention group). The suturing process on each side is completely random (Balanced Block Randomization method) and it means that the surgeon didn't apply his personal opinion for suturing (which side first and which suturing technique first). The point where the needle enters the tissue is far 3 mm from the edge of the wound. The surgical site is sutured with 0.3 Vikril absorbable (slowly absorb) suture (brand name: SUPABON made in Iran / SUPA company) with a 19 mm reverse cutting needle and a 3.8 gauge. Both side sutures will be remove 7 days after surgery. On surgery day, 7 days and 14 days after surgery intraoral photograph is taken. In the end intraoral photographs will be evaluate by impact assessor with AutoCAD software.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran university of medical sciences, international campus, school of dentistry

##### Full name of responsible person

Dr. Nima Dehghani

##### Street address

Tehran university of medical sciences (international campus, school of dentistry), Mahan St., Zam Zam

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Behrad Tanbakouchi

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**Grant name**

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**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Houra Astaneh

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nima Dehghani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Oral and Maxillofacial surgeon

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is 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**

Data file and statistical analysis will be shared.

**When the data will become available and for how long**

3 months after data collection

**To whom data/document is available**

The above information will be available to the public as an attachment of the published article.

**Under which criteria data/document could be used**

For better understanding of the study findings as well as a reference for future studies

**From where data/document is obtainable**

From website of the journal in which the article will be published.

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

The data file and statistical analysis will be available to everyone.

**Comments**

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