Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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

Tehran

Province

Tehran

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
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Sponsors / Funding sources

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Sponsor

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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
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 updating data

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Student
Latest degree
Medical doctor
Other areas of specialty/work
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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
