Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the scar formation using Vicryl rapide and Vicryl suture materials in Le-fort I osteotomy: A triple-blinded randomized clinical trial

Protocol summary

Study aim

evaluation and comparison of the amount of the mucosal scar following application of Vicryl Rapide and Vicryl suture materials in LeFort I osteotomy

Design

A triple-blinded clinical trial with parallel and split-mouth design, self-controlled and randomized with the study sample size of 26 patients. for randomization purposes, online computer-based software (www.randomization.com) will be used.

Settings and conduct

26 patients undergoing LeFort I osteotomy in Alzahra and Kashani teaching hospitals will be included. after performing the osteotomy, suturing the incision line will be performed using Vicryl Rapide and Vicryl suture materials on the right and left sides based on the randomized order in the sealed envelop for each patient.after 4 months, evaluation the scar tissue using the mucosal scarring index will be performed by three OMF surgeons. patients, outcome assessors, investigator, and data analyzer will be blinded by just access to the codes "A" and "B" allocated to the suture materials.

Participants/Inclusion and exclusion criteria

all patients undergoing LeFort I osteotomy for correction of their skeletal deformity are included in this study. any factor causing impaired wound healing and unusual scar formation excludes the patient from the study.

Intervention groups

after performing LeFort I osteotomy and based on the randomized order, the right side of the incision in the maxillary vestibular area will be sutured using one suture material (Vicryl Rapide or Vicryl) and the left side will be closed using another suture material (Vicryl or Vicryl Rapide). after 4 months the mucosal scar will be evaluated by three oral and maxillofacial surgeons using the mucosal scarring index. due to the split-mouth design, patients are self-control and there would not be any separate control group.

Main outcome variables

the mean score of the mucosal scarring index; type of the suture material

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131205015665N5**
Registration date: **2020-08-25, 1399/06/04**
Registration timing: **prospective**

Last update: **2020-08-25, 1399/06/04**
Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Milad Etemadi-Shalamzari

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

2020-08-31, 1399/06/10

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the scar formation using Vicryl rapide and Vicryl suture materials in Le-fort I osteotomy: A triple-blinded randomized clinical trial

Public title

Efficacy of Vicryl Rapide suture on the reduction of the scar formation after upper jaw surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients undergoing Le-fort I osteotomy for correction of skeletal deformity

Exclusion criteria:

age less than 18 or more than 40 pre-existing scar in vestibular area or history of surgery in maxillary vestibule any systemic and chronic disease which can interfere with wound healing process (i.e. diabetes, kidney and liver diseases) long-term corticosteroid or antibiotic therapy, or immunosuppressor drugs (specially in the last 6 month) congenital or acquired compromising immune system dehydration and malnutrition and associated neural defects (especially vitamin C and zinc deficiency) history of radiotherapy and using cytotoxic drugs tobacco use and alcoholism Fitzpatrick skin classification types I, IV, V, VI Maxillary advancement more than 6 mm history of allergic reaction (known or suspected) to suture materials

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **26**

More than 1 sample in each individual

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

In each patient, the right half of the incision (from the maxillary first molar to the mid-line) will be sutured with one suture material (vicryl or vicryl rapide based on a randomization plan) and the left half with the other suture material.

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization using online computer-based software (http://www.randomization.com) leading to a randomized plan in which the first suture will be used in the right side and the second suture on the left side of the surgery. unit of randomization is individual and by using a sealed envelop for each patient consisting of the order of suturing and suture materials, the right half of the incision (from the maxillary first molar to the mid-line) will be sutured with one suture material (vicryl or vicryl rapide based on randomization plan) and the left half with the other suture material.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patient: patients are not aware of the exact location of the suture materials. Outcome assessor: assessors are not aware of the exact location of the suture materials during the examination of the scar tissue. Investigator: The researcher will not be aware of the exact location of the suture materials and they will be only informed by the surgeons' registrations in the patients' form using "A" and "B" codes for suture materials. Data analyzer: analyzer won't be aware of the exact location of the suture materials and data is given to him/her coded as "A" and "B".

Placebo

Not used

Assignment

Parallel

Other design features

Split-mouth design: the right half of the incision (from the maxillary first molar to the mid-line) will be sutured with one suture material (vicryl or vicryl rapide based on randomization plan) and the left side with the other suture material.

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

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73461-81746

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.284

Health conditions studied

1

Description of health condition studied
Clinical evaluation of mucosal scar in maxillary vestibule using vicryl and vicryl rapide suture materials after Le-fort I osteotomy

ICD-10 code
Y74.3

ICD-10 code description
Surgical instruments, materials and general hospital and personal-use devices (including sutures) associated with adverse incidents

Primary outcomes

1

Description
Mean score of mucosal scarring index from 0 to 10

Timepoint
4 months after surgery

Method of measurement
using mucosal scarring index consisting of 5 parts of Width, Height or Contour, Color, Suture mark, and Overall appearance; each range from 0 to 2 scores. For reach patient, 3 surgeons will evaluate the tissue and the mean of scores will be reported for the left and right sides for each patient.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Considering an ID number from 1 to 26 for each patient, randomization is done using online computer-based software (http://www.randomization.com). The randomization plan is used as follows: "the first suture name is placed on the right side while the second one on the left side of the incision line". Le-fort I Osteotomy is done using a V-shaped incision in vestibular mucosa of the maxilla; 5 mm superior to the mucogingival junction from maxillary right first molar to the maxillary left first molar. after osteotomy and before suturing the incision line, alar base cinch technique using 3-0 nylon (Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey) suture material for preventing the widening of the base of the nose. due to the split-mouth design, the sealed envelop related to the patient's ID number is peeled open and the right side of the incision line from the maxillary right first molar to the mid-line is sutured with vicryl (Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey) or vicryl rapide (Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey) suture as mentioned in the randomization plan by continuous lock technique and in a tension-free manner.

Category
Treatment - Other

2

Description
Intervention group 2: Considering an ID number from 1 to 26 for each patient, randomization is done using online computer-based software (http://www.randomization.com). The randomization plan is used as follows: "the first suture name is placed on the right side while the second one on the left side of the incision line". Le-fort I Osteotomy is done using a V-shaped incision in vestibular mucosa of the maxilla; 5 mm superior to the mucogingival junction from maxillary right first molar to the maxillary left first molar. after osteotomy and before suturing the incision line, alar base cinch technique using 3-0 nylon (Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey) suture material for preventing the widening of the base of the nose. due to the split-mouth design, the sealed envelop related to the patient's ID number is peeled open and the left side of the incision line from the maxillary left first molar to the mid-line, is sutured with vicryl (Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey) or vicryl rapide (Ethicon Inc., Johnson and Johnson Company, Somerville, New Jersey) suture as mentioned in the randomization plan by continuous lock technique and in a tension-free manner.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani hospital

Full name of responsible person
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2

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Name of recruitment center
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
399230
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

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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
available for 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 "gtajmiri.gt@gmail.com".
What processes are involved for a request to access data/document
10 days after sending the request, data will be accessible.
Comments