# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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.

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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

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**2**

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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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Assistant professor
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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**