

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Clinical Evaluation of scar formation using VICRYL® RAPIDE and VICRYL® suture materials in genioplasty : A Thriple-blinded Randomized Clinical Trial

#### Protocol summary

##### Study aim

The purpose of this study is to compare the amount of scar tissue by using two type of vicryl and rapid vicryl in genioplasty surgery.

##### Design

Randomized Clinical Trial- a parallel study with split-mouth design

##### Settings and conduct

26 patients undergoing Genioplasty 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. after 4 months, evaluation the scar tissue using the mucosal scarring index will be performed by three maxillofacial surgeons.

##### Participants/Inclusion and exclusion criteria

all patients undergoing genioplasty 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

Intervention group 1: After randomization , 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". Genioplasty is done using Sliding technique. 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 right mandibular canin to the mid-line is sutured with vicryl or vicryl rapide suture as mentioned in the randomization plan Intervention group2:Genioplasty is done using Sliding technique. due to the split-mouth design the left side of the incision line from the left mandibular canin to the mid-line is sutured with vicryl or vicryl rapide suture as mentioned in the randomization plan

#### Main outcome variables

the mean score of the mucosal scarring index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131205015665N6**

Registration date: **2022-09-09, 1401/06/18**

Registration timing: **retrospective**

Last update: **2022-09-09, 1401/06/18**

Update count: **0**

##### Registration date

2022-09-09, 1401/06/18

##### 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

2022-03-06, 1400/12/15

##### Expected recruitment end date

2022-07-06, 1401/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Clinical Evaluation of scar formation using VICRYL® RAPIDE and VICRYL® suture materials in genioplasty : A Thriple-blinded Randomized Clinical Trial

**Public title**  
Efficacy of Vicryl Rapide suture on the reduction of the scar formation after genioplasty

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
patients undergoing Genioplasty 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

**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
- Data and Safety Monitoring Board

**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 mandibullar canin 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.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 mandibullar canin to the mid-line is sutured with vicryl or vicryl rapide suture as mentioned in the randomization plan by continuous lock technique and in a tension-free manner 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 and dissociation of suture material is not possible because the apparent feature of them are same . 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 mandibullar canin 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**

Isfahan University of Medical Sciences,Hezar-jerib st., Isfahan, Iran.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Approval date**

2022-02-21, 1400/12/02

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1400.469

**Health conditions studied**

## 1

### Description of health condition studied

mucosal scar in mandibular vestibule after Genioplasty

### ICD-10 code

Y81.3

### ICD-10 code description

General- and plastic-surgery devices associated with adverse incidents : surgical instruments, materials and devices (including sutures)

## 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 each 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, After randomization , 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". Genioplasty is done using Sliding technique and The initial cut is perpendicular to mucosa. Then, as muscle is transected, the angle of the cut is altered perpendicular to the bone and continued through the periosteum. At least 5 mm of attached periosteum and muscle are left between the inferior border of the symphysis and the subperiosteal dissection . before suturing the incision line, mentalis muscle each side sutured. 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 right mandibular canin 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 group2: Considering an ID number from 1 to 26 for each patient, After randomization , 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". Genioplasty is done using Sliding technique and The initial cut is perpendicular to mucosa. Then, as muscle is transected, the angle of the cut is altered perpendicular to the bone and continued through the periosteum. At least 5 mm of attached periosteum and muscle are left between the inferior border of the symphysis and the subperiosteal dissection . before suturing the incision line, mentalis muscle each side sutured. 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 left mandibular canin 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

Al-zahra hospital

##### Full name of responsible person

Etemadi Milad

##### Street address

Al-zahra hospital, Sofe Blvd, Isfahan

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##### Web page address

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### 2

#### Recruitment center

##### Name of recruitment center

Kashani hospital

##### Full name of responsible person

Milad Etemadi

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Kashani hospital , Ayatollah Kashani St, Isfahan

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mansoor Siavash

**Street address**

Vice-chancellor in research affairs, Isfahan University of Medical Sciences, Hezar jarib St, Isfahan, Iran

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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**

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

**Position**

Assist professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Assistant professor

**Latest degree**

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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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 isn't 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 6months 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 1996.f.baghery@gmail.cm

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

10 day after sending the request,data will be accessible

### **Comments**