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 mannerand 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

Isfehan

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 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,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 mussle 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 mussle 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
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 9273 7130
Email
Alzahra@mui.ac.ir
Web page address
http://Alzahra.mui.ac.ir

2

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Milad Etemadi
Street address
Kashani hospital ,Ayatollah Kashani St,Isfahan
City
Isfahan
Province
Isfehan
Postal code

8174673461

Phone
+98 31 9237 7130

Email
Kashani@mui.ac.ir

Web page address
http://kashani.mui.ac.ir

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

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 6836 3881

Email
research@mui.ac.ir

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

Street address
Department of oral and maxillofacial surgery, Dentistry Faculty, Isfahan University of Medical sciences, Hezar-jerib st., Isfahan, Iran.

City
Isfahan

Province
Isfehan

Postal code
817467361

Phone
+98 31 9237 8155

Email
Etemadi@dnt.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Milad Etemadi-Shalamzari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Hezar-jerib st., Esfahan

City
Esfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 1391 3237

Fax
+98 31 1391 3237

Email
etemadi@dnt.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Milad Etemadi Shalamzari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Department of oral and maxillofacial Surgery, Dentistry Faculty, Isfahan University of Medical Sciences, Hezar-jerib st., Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3792 5581

Email

etemadi@dnt.mui.ac.ir

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