

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparing the outcomes and complications of alar wedge excision and Serdev suturing techniques for alar base reduction surgery

Protocol summary

Study aim

Comparing the outcomes and complications of alar wedge excision and Serdev suturing techniques for alar base reduction surgery

Design

A randomized single-blind clinical trial study with a control group, with parallel design on 80 patients. Block randomization method will be used for randomization.

Settings and conduct

Khalili and Ghadir Mother and Child hospital affiliated to Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: age > 18 years, patients with primary surgery, absence of systemic and dermatologic diseases. Exclusion criteria: if patients did not returned follow-up visit after 12 months or had previous scar in site of alarplasty with any reasons.

Intervention groups

First group: patients who underwent Serdev suturing technique. Second group: patients who underwent alar wedge excision technique.

Main outcome variables

Duration of procedure; amount of bleeding; need for bleeding control

General information

Reason for update

Primary and secondary outcomes were entered instead of each other that corrected. Also, the study is single-blind because the patients were not blind.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131020015083N2**

Registration date: **2021-11-20, 1400/08/29**

Registration timing: **retrospective**

Last update: **2022-02-05, 1400/11/16**

Update count: **1**

Registration date

2021-11-20, 1400/08/29

Registrant information

Name

Amir Hossein Babaei

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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babaei@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the outcomes and complications of alar wedge excision and Serdev suturing techniques for alar base reduction surgery

Public title

Comparing of alar wedge excision and Serdev suturing techniques for alar base reduction surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age> 18 years Patients with primary surgery Absence of systemic and dermatologic diseases

Exclusion criteria:
Previous scar in the site of alarplasty

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly assigned to Serdev (number 0 in select case) or external wedge resection (number 1 in select case) groups (1: 1 ratio) using random numbers which were generated through computerized block randomization using SPSS software version 23. To reduce selection bias and confounding factors, randomization was performed by a single appointed researcher who did not participate in data collection.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessor, Investigator and statisticians who analyzed the data were unaware of the intervention and allocation of treatments until the statistical analysis was complete.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand Street

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2020-05-06, 1399/02/17

Ethics committee reference number
IR.SUMS.MED.REC.1399.064

Health conditions studied

1

Description of health condition studied
patients with large alar base

ICD-10 code
Z41.1

ICD-10 code description
Encounter for cosmetic surgery

Primary outcomes

1

Description
Scar formation

Timepoint
12 months after surgery

Method of measurement
Direct examination

2

Description
Satisfaction score

Timepoint
12 months after surgery

Method of measurement
ROE and PSAQ questionnaire

Secondary outcomes

1

Description
Amount of bleeding

Timepoint
Intra-operative

Method of measurement
Volume of bleeding (CC)

2

Description
Duration of procedure

Timepoint
Intra-operative

Method of measurement
Digital chronometer (sec)

3

Description
Need for bleeding control

Timepoint
Intra-operative

Method of measurement

Using electrocautery to stop bleeding

kaboodkhani@yahoo.com

Intervention groups**1****Description**

Intervention group: Serdev suturing technique

Category

Treatment - Surgery

2**Description**

Control group: External wedge resection

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ear, Nose and Throat Clinic, Khalili Hospital

Full name of responsible person

Dr Reza Kaboodkhani

Street address

khalili street

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Web page address**2****Recruitment center****Name of recruitment center**

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7144995377

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Fax**Email****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number**

98-01-01-21228

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Reza Kaboodkhani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions.

Under which criteria data/document could be used

there is no specified criteria

From where data/document is obtainable

corresponding author (09177395073, babaei@sums.ac.ir)

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

the request should be sent by email (containing personal and professional information), describing their study protocol, after approving their identity and proposal, the data will be sent by email.

Comments