Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of high-dose and low-dose hyaluronidase in the treatment of patients with vascular complications after hyaluronic acid filler injection

Protocol summary

Study aim
Comparison of the effectiveness of high-dose and low-dose Hyaluronidase in the treatment of vascular complications after hyaluronic acid filler injection

Design
This parallel randomized, double-blind, controlled trial will be conducted with a 1:1 allocation ratio (15 persons in each group). Patients will be randomly assigned to two groups of high and low-dose hyaluronidase through the block randomization method.

Settings and conduct
The patient and the final evaluator do not know the injected doses for each patient. The setting is Razi Hospital. To the patients in the high-dose hyaluronidase group with a high dose1500 units of hyaluronidase will injected and two hours later another 1500 units will injected. In the low-dose group, 300 units of hyaluronidase will injected in the necrotic areas, and two hours later, 300 units will injected again. The patient is then followed up 24 and 48 hours later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Vascular complication following hyaluronic acid filler injection in the face area; Occurrence of symptoms related to vascular complications (such as blanching, severe and sudden pain, Livedo reticularis, prolongation of capillary filling, ischemia, and necrosis); Exclusion criteria: Injection of fillers other than hyaluronic acid; Injection in areas other than the face; The patient's sensitivity to hyaluronidase; Hyaluronidase injection before going to the hospital; Patient dissatisfaction; The patient's need for additional treatments

Intervention groups
In the high-dose group, 1500 units of hyaluronidase will injected, and two hours later another 1500 units will be injected. In the low-dose group, 300 units of hyaluronidase will injected in the necrotic areas and two hours later another 300 units will be injected.

Main outcome variables
Scars; hypopigmentation; hyperpigmentation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241113063694N1**
Registration date: **2024-11-17, 1403/08/27**
Registration timing: **prospective**

Last update: **2024-11-17, 1403/08/27**
Update count: **0**

Registration date
2024-11-17, 1403/08/27

Registrant information

Name
Seyedeh Mohadeseh Mousavi Moghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 5288 8282

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-20, 1403/08/30

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of high-dose and low-dose hyaluronidase in the treatment of patients with vascular complications after hyaluronic acid filler injection

Public title
Comparison of the effectiveness of high-dose and low-dose Hyaluronidase in the treatment of patients with vascular complications after hyaluronic acid filler injection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Vascular complication following hyaluronic acid filler injection in the face area Occurrence of symptoms related to vascular complications (such as blanching, severe and sudden pain, Livedo reticularis, prolongation of capillary filling, ischemia and necrosis)
Exclusion criteria:
Injection of fillers other than hyaluronic acid Injection in areas other than the face The patient's sensitivity to hyaluronidase Hyaluronidase injection before going to the hospital Patient dissatisfaction The patient's need for additional treatments compared to research
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups of high and low-dose Hyaluronidase through the block randomization method. A trained research assistant uses this method for randomization. Block size will be equal to 4 with equal probability to assign patients in each group (high dose group (group B) and low dose (group A). According to the size of the blocks, we have six possible permutations including AABB, ABAB, BAAB , we will have BABA, BBAA, and ABBA.At first, the assistant will randomly select one of these blocks, and four eligible patients will be determined based on that in each block. We will repeat this process many times Eligible patients are included in the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
Although patients will be informed of our primary goals, they will not know which drug they will receive. Due to the difference in the dose injected to the patients, it is not possible to blind the resident who is responsible for injecting the drug. The final evaluation is done by a skin and hair disease specialist using the clinical evaluation of the appearance of the lesion and the patient's symptoms. It should be mentioned that the final evaluator does not know the injected doses for each patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Keshavarz Blvd., intersection of Qods St., Central Building of Tehran University of Medical Sciences, sixth floor, room 604
City
Tehran
Province
Tehran
Postal code
1461884513
Approval date
2024-05-29, 1403/03/09
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.077

Health conditions studied

1

Description of health condition studied
Patients who suffered vascular complications following hyaluronic acid filler injection
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Any skin effects that remain from the initial lesion, such as scars, hypopigmentation, hyperpigmentation
Timepoint
Follow-up of patients in both groups is evaluated at 24

hours, 48 hours, one week, one month, and three months after the injection

Method of measurement

The clinical outcome is considered as Favorable outcome, Borderline outcome, Unfavorable outcome. Favorable outcome is the complete healing of the lesion and wound without leaving any scars or hypohyperpigmentation. Borderline outcome includes the complete healing of the lesion without leaving a scar with hypohyperpigmentation and Unfavorable outcome is the formation of a scar regardless of other symptoms.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To the patients who are placed in the hyaluronidase group with a high dose ,1500 units of hyaluronidase will inject with a needle, two hours later another 1500 units will inject.

Category

Treatment - Drugs

2

Description

Control group: In the low dose group, 300 units of hyaluronidase will injected in the necrotic areas, and two hours later, 300 units will injected again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Seyedeh Mohadeseh Mousavi Moghadam

Street address
Tehran, Vahdat Eslami Street, Vahdat Eslami Square, Razi Dead End, Razi Skin Specialist Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Hamidreza Mahmoudi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Tehran-Vahdat-Islami St.-Vahdat-Islami Square-Razi Dead End-Razi Skin Specialist Hospital

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Specialist
Other areas of specialty/work
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Person responsible for updating data

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Dermatology resident
Latest degree
Medical doctor
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Dermatology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available