Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of side effects (sensitivity and redness, tissue necrosis, accumulation of mass under the skin) caused by injection of Hyaluronic Acid dermal fillers of two brands, Restylane and Perfectha, under the eye area of patients referred for skin rejuvenation.

Protocol summary

Study aim
Comparison and determination of side effects caused by the injection of hyaluronic acid dermal fillers of two brands,Restylane and Perfectha, under eye area among patients referred to Amirul Mominin Hospital in 2023 in Tehran

Design
Clinical trial, with parallel groups, single-blind, non-randomized, phase 4 on 86 patients. The clinical trial has two intervention groups of 43 people, group number one receiving Restylane filler and group number two receiving Perfectha filler in the under eye area.

Settings and conduct
The place of study: Dermatology department of Amir Al-Mominin Hospital in Tehran. The study population: patients referred for skin rejuvenation. Blinding: not done in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: complete patient information; informed Consent; Age over 18 years and under 70 years.
Exclusion criteria: Presence of underlying disease; History of similar injections in the past under the eyes

Intervention groups
Intervention group 1: Recipient of Restylane filler, 0.5 to 1 ml of filler is injected with a 32 gauge needle in the orbit rim. Intervention group 2: recipient of Perfecta filler, 0.5 to 1 ml of filler is injected with a 32-gauge needle in the orbital rim.

Main outcome variables
sensitivity and redness; Mass accumulation under the skin; skin necrosis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230724058912N1**
Registration date: **2023-09-02, 1402/06/11**
Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**
Update count: **0**

Registration date
2023-09-02, 1402/06/11

Registrant information

Name
Ensie Keshvari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3371 4516

Email address
keshvari75@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-06, 1402/06/15

Expected recruitment end date
2023-11-06, 1402/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of side effects (sensitivity and redness,

tissue necrosis, accumulation of mass under the skin) caused by injection of Hyaluronic Acid dermal fillers of two brands, Restylane and Perfectha, under the eye area of patients referred for skin rejuvenation.

Public title
Comparison of side effects caused by injection of Hyaluronic acid dermal fillers of two brands, Restylane and Perfectha, in the under eye area

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hyaluronic acid injection in the under eye area age between 18 to 70 informed consent

Exclusion criteria:
History of bleeding diseases History of eye surgery in the last month

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants in both groups remain unaware of the treatment method allocation during the study. The patient is informed that there are two types of hyaluronic acid gel brands in a study and they will receive one of them randomly. Patients remain unaware of the name of the treatment method assigned to them.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University of Medical Sciences

Street address
Tehran branch of Islamic Azad University of Medical Sciences, Khaghani st, Shariati st

City
Tehran

Province
Tehran

Postal code
1916893813

Approval date
2023-04-17, 1402/01/28

Ethics committee reference number
IR.IAU.TMU.REC.1402.045

Health conditions studied

1

Description of health condition studied
Complications caused by injecting hyaluronic acid dermal fillers in the under eye area

ICD-10 code
T50.995

ICD-10 code description
Adverse effect of other drugs, medicaments and biological substances

Primary outcomes

1

Description
Inflammation and redness of the area based on the dermatologist examination

Timepoint
7 days, one month and two months after hyaluronic acid injection

Method of measurement
The opinion of two dermatologist separately

2

Description
Mass accumulation under the skin

Timepoint
7 days, one month and two months after hyaluronic acid injection

Method of measurement
The opinion of two dermatologist separately

3

Description
skin necrosis

Timepoint
7 days, one month and two months after hyaluronic acid injection

Method of measurement
The opinion of two dermatologist separately

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: the group of 43 people receiving Restylane filler, Restylane filler, which is made of non-animal hyaluronic acid and is produced by a Swedish company in packages of one milliliter volume, in the amount of half to one milliliter depending on the needs of the patients. We inject in the orbital rim using a 32-gauge needle or cannula within twenty minutes.

Category
Treatment - Drugs

2

Description
The second intervention group: the group of 43 people receiving Perfecta filler, Perfecta filler is made of non-animal hyaluronic acid and is produced by a French company in packages of one milliliter volume, half to one milliliter depending on the needs of the patients. We inject the orbital rim using a 32-gauge needle or cannula within twenty minutes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Al-Momenin Hospital

Full name of responsible person
Ensie Keshvari

Street address
Shirmohammadi street, Nazi-abad

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Masoud Parsania

Street address
No 403, Tehran West Unit Building, Ayeneh Blvd., Pabarja St., Qolhak Road, Shariati St., District 3

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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Ensie Keshvari

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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