

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1811694784

##### Phone

+98 21 5534 6550

##### Email

amhos@iautmu.ac.ir

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1774684343

#### Phone

+98 912 202 4729

#### Email

keshvari75@yahoo.com

#### 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

##### Street address

No 9 ; Motebaheri avenue ; Ayatollah Saeedi square;  
Akbarabadi avenue

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Tehran

##### Province

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##### Phone

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##### Fax

##### Email

keshvari75@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

**Full name of responsible person**

Setare Tehrani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

No 2; at the corner of Sarv street; Afriqa street

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**Province**

Tehran

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**Email**

tehrani249@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Setare Tehrani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

No 2; at the corner of Sarv street; Afriqa street

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**Province**

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**Postal code**

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**Email**

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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