

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Evaluation of safety and effectiveness of liposomal hyaluronic acid, PRP and vitamin C in rejuvenation and brightening under the eyes

#### Protocol summary

##### Study aim

Evaluation of safety and effectiveness of liposomal hyaluronic acid, PRP and vitamin C in rejuvenation and brightening under the eyes

##### Design

Phase 1-2, non-random assignment to intervention and control groups, 3 intervention groups and 6 control groups, single blind, parallel

##### Settings and conduct

This study is conducted at the Skin and Stem Cell Research Center in the field of treating dark circles under the eyes. Three products will be evaluated locally in three intervention groups with 6 local control groups along with the microneedling method. The evaluator will be blinded to the data.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: darkness and wrinkles in the lower eyelid area, which need to be treated according to the opinion of the hospital doctor and the patient's desire.  
exclusion criteria: patients who had undergone previous surgery in the eyelid area, have had previous minimally invasive treatments such as botulinum toxin or fillers in the eyelid area.

##### Intervention groups

Intervention group: patients use liposomal hyaluronic acid topically daily for three months. Control group: patients use liposomal platelet-rich plasma product topically for three months. Control group: patients receive platelet-rich plasma products three times with a one-month interval after performing microneedling locally. Intervention group: patients use liposomal vitamin C topically daily for three months. Control group: patients receive topical vitamin C product three times with an interval of one month after performing microneedling. Control group: patients use hyaluronic acid topically daily for three months. Control group: patients use platelet rich plasma topically daily for three months. Control group: patients use vitamin C topically daily for three months.

##### Main outcome variables

Darkness under the eyes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046282N28**

Registration date: **2023-05-06, 1402/02/16**

Registration timing: **prospective**

Last update: **2023-05-06, 1402/02/16**

Update count: **0**

##### Registration date

2023-05-06, 1402/02/16

##### Registrant information

##### Name

Sona Zare

##### Name of organization / entity

Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2665 7438

##### Email address

sonazarebio@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-10, 1402/02/20

##### Expected recruitment end date

2023-08-11, 1402/05/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of safety and effectiveness of liposomal hyaluronic acid, PRP and vitamin C in rejuvenation and brightening under the eyes

**Public title**

Evaluation of safety and effectiveness of liposomal hyaluronic acid, PRP and vitamin C in rejuvenation and brightening under the eyes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Darkness and wrinkles in the lower eyelid area, which need to be treated according to the opinion of the hospital doctor and the patient's desire.

**Exclusion criteria:**

Patients who had undergone previous surgery in the eyelid area Have had previous minimally invasive treatments such as botulinum toxin or fillers in the eyelid area. Patients with active skin disorders or inflammation, acute or chronic infection, tumors or cancer Patients under anticoagulant treatment smokers

**Age**

From **21 years** old to **60 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The data evaluator is given a general explanation of the study, but one method is not presented as superior to another, and no preference is given to one of the interventions. As a result, this person is blind to the effect of the intervention. The patient and the doctor will not be blinded and will know about the study groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Keshavarz blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Approval date**

2022-10-10, 1401/07/18

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1401.538

**Health conditions studied****1****Description of health condition studied**

Darkening under the eye

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The amount of darkness under the eyes

**Timepoint**

prior to treatment, three and six months after the last treatment session

**Method of measurement**

VisioFace device

**2****Description**

The amount of wrinkles under the eyes

**Timepoint**

prior to treatment, three and six months after the last treatment session

**Method of measurement**

Visioface

**Secondary outcomes****1****Description**

Patient satisfaction

**Timepoint**

prior to treatment, three months and six months after the last treatment session

## Method of measurement

Standard questionnaires visual analogue scale (VAS)

## Intervention groups

### 1

#### Description

Intervention group: Patients use 1 cc liposomal hyaluronic acid (Zist Sakht Bonyan Pars Company) products topically in the area under the eyes once a day for three months.

#### Category

Treatment - Other

### 2

#### Description

Control group: Patients receive 1 cc hyaluronic acid products (Zist Sakht Bonyan Pars Company) locally in the clinic three times with an interval of one month after performing microneedling.

#### Category

Treatment - Other

### 3

#### Description

Intervention group: Patients use 1 cc liposomal platelet-rich plasma (Zist Sakht Bonyan Pars Company) products topically in the under-eye area once a day for three months.

#### Category

Treatment - Other

### 4

#### Description

Control group: Patients receive 1 cc platelet-rich plasma product (Zist Sakht Bonyan Pars Company) locally in the clinic three times with an interval of one month after microneedling.

#### Category

Treatment - Other

### 5

#### Description

Intervention group: Patients use 1 cc liposomal vitamin C (Zist Sakht Bonyan Pars Company) topically in the area under the eyes once a day for three months.

#### Category

Treatment - Other

### 6

#### Description

Control group: Patients receive 1 cc vitamin C product (Zist Sakht Bonyan Pars Company) topically in the area under the eyes three times with an interval of one month after performing microneedling.

#### Category

Treatment - Other

### 7

#### Description

Control group: Patients use the 1 cc non- liposomal hyaluronic acid (Zist Sakht Bonyan Pars Company) product topically in the area under the eyes once a day for three months.

#### Category

Treatment - Other

### 8

#### Description

Control group: Patients use 1 cc non- liposomal platelet-rich plasma (Zist Sakht Bonyan Pars Company) product topically in the under-eye area once a day for three months.

#### Category

Treatment - Other

### 9

#### Description

Control group: Patients use 1 cc non- liposomal vitamin C (Zist Sakht Bonyan Pars Company) product topically in the area under the eyes once a day for three months.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Nilforoushzadeh

##### Street address

No 4, Maryam Alley, South Kamraniyeh Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

##### Phone

+98 21 2665 7438

##### Email

Dr\_nilforoush@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Akbar Fatuhi

##### Street address

Keshavarz Blvd., corner of Qods St., Central

University Organization, floor 6th vice president of research and technology

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**Province**

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**Phone**

+98 21 81631

**Email**

ir.ac.tums@vcr

**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**

Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences

**Full name of responsible person**

Sona Zare

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cellular and Molecular Biology

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

**Contact****Name of organization / entity**

Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences

**Full name of responsible person**

Sona Zare

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cellular and Molecular Biology

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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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable