Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Postal code
1937957511
Phone
+98 21 2665 7438
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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

City
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Province
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1937957511

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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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No 4, Maryam Alley, South Kamraniyeh Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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

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Full name of responsible person
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Position
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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