

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigation the effect of platelet Rich fibrin matrix in correction of periorbital wrinkles

Protocol summary

Study aim

Use of platelet-rich fibrin matrix for correction of periorbital wrinkles.

Design

Clinical trial without control group, without randomization, phase 2 on 16 cases. According to the pilot study and work on the human sample & analysis (type 1 error 0.05, type 2 error 0.2, effect size 0.58 using cochrain formula) the sample size of 16 cases was considered. Any patient who goes to the clinic and wants to participate in the project will be included.

Settings and conduct

All procedures are performed by a doctor in the dermatology clinic of Shahid Faghihi Hospital in Shiraz. For intervention, initially, 15 ml of autologous blood from the brachial vein will be taken from each patient in sterile conditions and is entered into special tubes, and then is centrifuged for five minutes with 700 RPM. The resulting gel, which consisted of 3cc PRF, will be injected into the subdermal area on both sides. The initial severity of periorbital wrinkles will be determined by Visioface 1000D (CK electronic, manufactured in Germany), and will subsequently be evaluated in each visit both prior to and after PRF injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult people over 30 years old; with facial aging. Exclusion criteria: history of warfarin or ASA administration, immunomodulatory medications; any medical problem such as connective tissue disorders.

Intervention groups

Eight adult women and men over the 30-year-old with facial wrinkles will be studied in one group. After blood sampling and centrifugation at a speed of 700rpm for 5 minutes, the platelet-rich fibrin will be injected into the periorbital wrinkles on both sides. The depth of wrinkles before and 12 weeks after will be measured by visioface device.

Main outcome variables

The main variable is the depth of periorbital wrinkles .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220218054054N1**

Registration date: **2022-03-12, 1400/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-12, 1400/12/21**

Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

Mohammadreza Namazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 302 7858

Email address

namazi_mr@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-08, 1400/12/17

Expected recruitment end date

2022-03-17, 1400/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of platelet Rich fibrin matrix in correction of periorbital wrinkles

Public title

Rejuvenation with PRF

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Any adult over 30 with facial wrinkles

Exclusion criteria:

History of anticoagulant Administration such as warfarin and ASA History of immunomodulatory medications

History of a medical problem such as connective tissue disorders Pregnancy

Age

From **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand st.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.SUMS.MED.REC.1400.480

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

face aging

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

Skin facial aging

Timepoint

Prior and 12 weeks after PRF injection.

Method of measurement

visioface device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:At first photography will be taken by Visioface 1000 D (CK electronic, manufactured in Germany) and after PRF injection (3month) photography will be taken again.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faghihi hospital

Full name of responsible person

Razieh Ahmadi Mahmoodabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz 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

Shiraz University of Medical Sciences

Proportion provided by this source

3

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**

Shiraz University of Medical Sciences

Full name of responsible person

Razieh Ahmadi Mahmoodabadi

Position

student

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Specialist

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Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadreza Namazi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Fax**Email**

Namazi_mr@yahoo.com

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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Data on the main outcome can be shared.

When the data will become available and for how long

9 months after results writing.

To whom data/document is available

just researcher committee

Under which criteria data/document could be used

to do relevant and complementary research. no name and personal details.

From where data/document is obtainable

razieh ahmadi mahmoodabadi md by written request .

What processes are involved for a request to access data/document

agree to ethical standards and permission of the associated professor

Comments