Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 0.58using cocrain 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)

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+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
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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
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Person responsible for updating data

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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
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 resulte writing.
To whom data/document is available
just reasercher committee
Under which criteria data/document could be used
to done 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