Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of injection of cellular plasma gel with skin fibroblasts in skin rejuvenation

Protocol summary

Study aim
Investigation the effect of injection of cellular plasma gel with skin fibroblasts in skin rejuvenation

Design
Clinical trial without control group, community based, not blinded, Non-randomised controlled study

Settings and conduct
This study is related to dermatology field and will be done in Afzali pour hospital and Cell Therapy and Regenerative medicine Comprehensive Center of Kerman University of medical sciences. After case selection by physician, skin sample is isolated and cultured. After preparation of cellular plasma gel with fibroblasts, it will be injected by physician to patient. Injection will be done 3 times with the period of 3 months and 2 months after the last injection skin alternations of patient will be evaluated.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Presence of aging signs of skin with grade 3 or 5 2. Patients aged between 30-50 years 3. Patients desire to biopsy Exclusion Criteria: 1. Individuals with systematic or local retinoid medications. 2. Patients with history of hemorrhagic disorders or patients who received anticoagulant treatment recently 3. Any factors that inhibit low invasive techniques 4. Patients with autoimmune diseases. 5. Doing skin procedures and racer-facing lasers

Intervention groups
Skin fibroblasts with plasma gel prepared from own patient, 3 times with the interval of every 3 months is injected into patient's skin and after 2 months from the last injection, skin alternation is evaluated.

Main outcome variables
Improvement in elasticity, moisture, pigmentation distribution, sebum activity, oil and wrinkle of skin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140911019125N5**
Registration date: **2020-03-05, 1398/12/15**
Registration timing: **prospective**

Last update: **2020-03-05, 1398/12/15**
Update count: **0**

Registration date
2020-03-05, 1398/12/15

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 32 24618
Email address
afarsinejad@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-04, 1399/01/16

Expected recruitment end date
2021-10-10, 1400/07/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of injection of cellular plasma gel with skin fibroblasts in skin rejuvenation

Public title

Study the effect of injection of plasma gel contained with skin fibroblasts in rejuvenation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of aging signs of skin with grade 3 or 5 Patients aged between 30-50 years Patients desire to biopsy

Exclusion criteria:

Individuals with systematic or local retinoid medications. Patients with history of hemorrhagic disorders or patients who received anticoagulant treatment recently Any factors that inhibit low invasive techniques Patients with autoimmune diseases. Doing skin procedures and racer-facing lasers

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Haft Bagh Blvd, Kerman University Of Medical Science

City

Kerman

Province

Kerman

Postal code

7616911333

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.KMU.REC.1398.645

Health conditions studied

1

Description of health condition studied

Skin Rejuvenation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Skin Elasticity

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Specific Equipment

2

Description

Skin Moisture

Timepoint

Before intervention and 2 month after intervention

Method of measurement

Specific Equipment

3

Description

Skin Pigmentation distribution

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Specific Equipment

4

Description

Sebum Activity

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Specific Equipment

5

Description

Skin oil

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Specific Equipment

6

Description

Skin Wrinkle

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, after sampling from patient and isolation of skin fibroblasts, plasma gel is prepared and coated with cells and injected into specific site of patient's skin.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Azadeh Mohebbi
Street address
Imam Khomeini Highway, Afzali pour Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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abpardakhty@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Alireza Farsinejad
Position
Assistant Professor
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Person responsible for updating data

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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
There is no additional data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In our study non of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared.
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
The data will be available for people working in academic institutions and clinicians.
Under which criteria data/document could be used
Applicants are only allowed to use received data in clinical and they are not allowed to published them
From where data/document is obtainable
1- Phone: 034-31325374 2- e-mail: afarsinejad@kmu.ac.ir 3- Fax: 034-31325375 4- address: Haft bagh Blvd, Kerman university of medical science Dr. Alireza Farsinejad
What processes are involved for a request to access data/document
Applicant can receive information after contact and send e-mail up to 10 days.
Comments