

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparing the effect of RF fractional laser and Microneedling on Skin rejuvenation, Skin's open pores and Skin lightening

Protocol summary

Skin rejuvenation, Skin's open Pores, Skin lightening

Study aim

Comparing the effect of RF fractional laser and microneedling on skin rejuvenation, skin's open pores and skin lightening

Design

This clinical trial has two intervention groups, with parallel groups, non-random sample selection and the choice of treatment for ethical considerations is the choice of patients themselves.

Settings and conduct

25 people in each group enter each of the intervention groups according to the inclusion criteria (Location: Dr. Mamizadeh Dermatology Clinic). Finally, after the treatment, the two groups are compared in terms of Skin open Pores, skin lightening and rejuvenation. Microneedling will be performed by Amiea device in 3 treatment sessions with three-week intervals. Fractional RF laser will be performed by Secret device in 3 sessions at 4-week intervals. Depending on the patient's condition such as age and location of the lesion, The device cartridge and the target depth will be adjusted

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in reasearch, Age range 20 to 50 years, Absence of inflammatory Skin disease, No history of psychiatric disordes, No history of recurrent herpes, No history of Colloidization, Absence of underlying diseases, Do not have a history of treatment with Microneedling and RF fractional Laser Exclusion criteria: Patients who do not want to continue treatment, Simultaneous use of drugs affecting the skin and other methods of rejuvenation, Having active acne

Intervention groups

In the first group, there are 25 people who want to rejuvenate the skin, close open pores and lighten the skin at the same time by microneedling method. In the first group, there are 25 people who want to rejuvenate the skin, close open pores and lighten the skin at the same time by fractional RF Laser method.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211212053366N1**

Registration date: **2022-01-05, 1400/10/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-05, 1400/10/15**

Update count: **0**

Registration date

2022-01-05, 1400/10/15

Registrant information

Name

Mohammad Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3224 8022

Email address

mohammadj2233@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-28, 1400/10/07

Expected recruitment end date

2022-01-27, 1400/11/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of RF fractional laser and Microneedling on Skin rejuvenation, Skin's open pores and Skin lightening

Public title

Comparing the effect of RF fractional laser and Microneedling on Skin rejuvenation, Skin's open pores and Skin lightening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in reasearch
Absence of inflammatory Skin disease
No history of psychiatric disorders
No history of Colloidization
Absence of underlying diseases such as Diabetes and Rheumatic diseases
Do not have a history of treatment with Microneedling and RF fractional Laser
Age range 20 to 50 years
No history of recurrent herpes

Exclusion criteria:

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Ilam University of Medical Sciences

Street address

Ethics committee, Ilam University of Medical Sciences, pazhuhesh Blvd

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.MEDILAM.REC.1400.154

Health conditions studied

1

Description of health condition studied

Skin rejuvenation, Skin's open Pores and Skin lightening

ICD-10 code

L98.8

ICD-10 code description

Other specified disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description

Skin rejuvenation

Timepoint

In 3 Visits with 3 week intervals

Method of measurement

Researcher made Questionnaire

2

Description

Skin's open Pores

Timepoint

In 3 Visits with 3 week intervals

Method of measurement

Researcher made Questionnaire

3

Description

Skin lightening

Timepoint

In 3 Visits with 3 week intervals

Method of measurement

Researcher made Questionnaire

Secondary outcomes

1

Description

Skin Spots after treatment

Timepoint

One week after the last treatment session

Method of measurement

Researcher made Questionnaire

2

Description

Bruising after treatment

Timepoint

One week after the last treatment session

Method of measurement

Researcher made Questionnaire

3

Description

Erythema after treatment

Timepoint

One week after the last treatment session

Method of measurement

Researcher made Questionnaire

4

Description

Swelling after treatment

Timepoint

One week after the last treatment session

Method of measurement

Researcher made Questionnaire

Intervention groups

1

Description

Intervention group 1: In the first group, there are 25 people who want to rejuvenate the skin, close open pores and lighten the skin simultaneously by microneedling. Microneedling will be performed by Amiea device in 3 treatment sessions with three-week intervals. Depending on the patient's condition, such as age and location of the cartridge, the device and the target depth will be adjusted.

Category

Treatment - Devices

2

Description

Intervention group 2: In the second group, there are 25 people who want to rejuvenate the skin, close open pores and lighten the skin simultaneously with fractional RF laser method. Fractional RF laser will be performed by Secret device in 3 sessions with 4-week intervals. Depending on the patient's condition, such as age and location of the cartridge, the device and the target depth will be adjusted.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mamizadeh Dermatology and Beauty Clinic

Full name of responsible person

Mina Mamizadeh

Street address

Clinic Dr Mamizadeh, Rashidi Alley, Saadi Ave
Ayatollah Heydari Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Kafashian

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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

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Jamali

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Unit 6, Aria Building, Nasim 1 Alley, Shahrvand Ave,
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Fax**Email**

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Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Dr Mina Mamizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Jamali

Position

Medical student

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

If specify the type of study and how to use the data in accordance with the rules of Ilam University of Medical Sciences

From where data/document is obtainable

Dr Mohammad Jamali mohammadj2233@gmail.com

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

After the request and notification of the research deputy, action will be taken as soon as possible

Comments