

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the Combined Therapeutic Effect of Mesotherapy and Fractional RF with Mesotherapy alone in eliminating Double Chin in Patients

Protocol summary

Study aim

Comparison of the combined therapeutic effect of mesotherapy and Fractional RF with mesotherapy alone in eliminating acne in the studied population based on (age, gender, body mass index, patient satisfaction, doctor's consent)

Design

A clinical trial with an intervention and control group, with parallel groups, single blind, randomized, on 100 patients.

Settings and conduct

This study will be conducted in the form of a clinical trial in two intervention and control groups in a single-blind manner on patients with gout, referring to dermatology clinics affiliated to Tehran Islamic Azad University of Medical Sciences. Using the combination of mesotherapy and Fractional RF methods for the intervention group of 50 people on even days of the participants and the treatment of gout by mesotherapy only for the control group of 50 people on odd days.

Participants/Inclusion and exclusion criteria

Eligibility criteria: willingness to participate in the study; age between 18 and 60 years old; lack of skin sensitivity. Exclusion criteria: existence of a known systemic disease affecting healing, such as type 2 diabetes; lack of consent to continue participating in the study; skin allergies when using the treatment; patients with underlying skin problems.

Intervention groups

Acne treatment using the combination of mesotherapy and Fractional RF for the intervention group of 50 people on even days and acne treatment by mesotherapy only for the control group of 50 people on odd days will be held in this study to treat acne with the mesotherapy method of Deoxy drug. Cholic acid and Scarlett device is used in fractional RF treatment.

Main outcome variables

Non-surgical treatment, creating a normal and beautiful appearance, avoiding the cost and complications of surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220615055190N1**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Seyedeh sara Sarhadi podonak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2262 2877

Email address

sarayy.sarhadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Combined Therapeutic Effect of Mesotherapy and Fractional RF with Mesotherapy alone in eliminating Double Chin in Patients

Public title

Effect of Mesotherapy and RF laser in the Treatment of Double chin

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to Participate in The Study Age between 18 to 60 years old Insensitivity of The skin

Exclusion criteria:

Existence of Known systemic disease Affecting repair such as type 2 diabetes Dissatisfaction With continuing to participate in the study Skin allergies when using the treatment Patient with underlying skin problems

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple random. People were randomly divided into two intervention groups with the help of a random number table and witnesses will be divided.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study,the person responsible for data collection and the data safety and monitoring committee are kept blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran Azad University of Medical Sciences

Street address

No 61,West dolatshad Alley,Farid Afshar ST,Zafar Ave,Modares Highway,Tehran,Iran

City

Tehran

Province

Tehran

Postal code

1916618661

Approval date

2022-06-13, 1401/03/23

Ethics committee reference number

IR.IAU.TMU.REC.1401.070

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

Treatment of Double chin

ICD-10 code

O32.3

ICD-10 code description

Maternal care for face, brow and chin presentation

Primary outcomes**1****Description**

The amount of drooping under the chin (ghabghab) according to the checklist

Timepoint

At the beginning of the study, 90, 120 days later

Method of measurement

According to the changes made in the photo registration

Secondary outcomes

empty

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

Intervention group: combination of two methods of mesotherapy, which uses deoxycholic acid in 6 sessions every two weeks and fractional RF from the Scarlet machine, which uses radiofrequency waves with fractional technology in 4 sessions every one month.

Category

Treatment - Devices

2

Description

Control group: For the control group, only mesotherapy is performed, in which deoxycholic acid drug is used in 6 sessions every two weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Serare Tehrani

Street address

Front of Sardarjangan Park, Naziabad

City

Tehran

Province

Tehran

Postal code

1811694784

Phone

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Email

sarayy.sarhadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad hashemian

Street address

Tehran Azad Islamic University of Medical Sciences building, corner of Gol Yakh St., Dr. Shariati St

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

seyede sara arhadi podonak

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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No 61, West dolatshad Alley, Farid Afshar St., Zafar Ave., Modares Highway

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyede Sara Sarhadi Podonak

Position

medical student

Latest degree

Medical doctor

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
doctor

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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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