

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

To evaluate the safety and efficacy of M3D Fractional - Made By Medaria in reducing facial aging: A single arm phase III clinical trial

Protocol summary

Summary

This is a single-arm phase III clinical trial will be performed on 15 subjects who are undergoing skin rejuvenation at Center for Research & Training Skin Diseases& Leprosy, Tehran University of Medical Sciences, Tehran, Iran. Each patient will be received six sessions of m3D Fractional treatment to the whole face. The face will be thoroughly cleaned and dried before treatment. Treatment will be conducted by trained and experienced technician according to the instructions in m3D Fractional user manual. All subjects will be asked to return for follow-up 1 week, 3 months and 6 months after their final treatment session. Digital photographs will be taken by VisioFace and subjects will be assessed for the degree of wrinkles and laxity at baseline and follow-up visits (1week, 3 months and 6 months after their final treatment session). Also Cutometer, Corneometer, TEWAmeter, Mexameter, and ultrasonographic measurements will be determined at baseline and follow-up visits. Subjects will rate overall satisfaction based on a 6-point Likert scale (0-No satisfaction, 1- very little satisfaction, 2-little satisfaction, 3-moderate satisfaction, 4-much satisfaction, 5- very much satisfaction) after the final treatment session and at follow-up visits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507226135N5**

Registration date: **2015-07-24, 1394/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name

Hamed Hosseini

Name of organization / entity

Clinical Trial Center (CTC),Tehran University of Medical Sciences (TUMS)

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 3546

Email address

hhosseini@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Medaria company

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the safety and efficacy of M3D Fractional - Made By Medaria in reducing facial aging: A single arm phase III clinical trial

Public title

To evaluate the safety and efficacy of M3D Fractional - Made By Medaria in reducing facial aging

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: • Aged between 30 to 60 years. • Mild to moderate (Glogau Score) • Skin Type (II-IV) • Signed

informed consent voluntarily and knowingly Exclusion criteria • History of any implant in face area • History of any cosmetic surgery during last 3 years in face area • History of RF during last year • History of any Botulinum, laser, or intense pulsed light during last 6 month • History of Isotretinoin during last 6 month • Collagen vascular disease • Diabetes • Severe cardiac disease • Malignant tumor • Bleeding disorders, Coagulopathy, any drugs affect bleeding time • Any active, chronic and recurrent infection • Any history of anaphylaxis • Susceptibility to keloids • Any active or recurrent herpes • Any immune-compromised conditions • Skin atrophy • Active smoker (last 2 years) • Pregnancy/ breast feeding • Vascular disease • Cardiac pace maker • Vertigo, labyrinthitis • Dyslipidemia

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd, Tehran

City

Tehran

Postal code

Approval date

2015-07-04, 1394/04/13

Ethics committee reference number

IR.TUMS.REC.1394.324

Health conditions studied

1

Description of health condition studied

Facial aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

wrinkle

Timepoint

At baseline- 1 week, 3 months and 6 months after the last treatment session

Method of measurement

Two board-certified dermatologists will perform clinical assessments in a blinded fashion by scoring every photograph according to the Fitzpatrick wrinkle scale

2

Description

laxity

Timepoint

At baseline- 1 week, 3 months and 6 months after the last treatment session

Method of measurement

Two board-certified dermatologists will perform clinical assessments in a blinded fashion by scoring every photograph according to the Alexiades-Armenakas laxity scale

Secondary outcomes

1

Description

Patient's overall satisfaction

Timepoint

At the final treatment session and at 1-week, 3- month and 6- month after their final treatment session

Method of measurement

based on a 6-point Likert scale (0-No satisfaction, 1- very little satisfaction, 2-little satisfaction, 3-moderate satisfaction, 4-much satisfaction, 5- very much satisfaction)

2

Description

Skin elasticity

Timepoint

At baseline and 1-week, 3- month and 6-month after the final treatment session

Method of measurement

Cutometer

3

Description

Water content

Timepoint

At baseline and 1-week, 3- month and 6-month after the final treatment session

Method of measurement

Corneometer

4**Description**

Transepidermal water loss

Timepoint

At baseline and 1-week, 3- month and 6-month after the final treatment session

Method of measurement

TEWAmeter

5**Description**

Skin pigmentation

Timepoint

At baseline and 1-week, 3- month and 6-month after the final treatment session

Method of measurement

Mexameter

6**Description**

Ultrasonographic measurements (skin thickness and density)

Timepoint

At baseline and 1-week, 3- month and 6-month after the final treatment session

Method of measurement

Skin ultrasonography

7**Description**

wrinkles and colour differences

Timepoint

At baseline and 1-week, 3- month and 6-month after the final treatment session

Method of measurement

VisioFace

8**Description**

Side-effects including erythema, edema, pain, hyperpigmentation and scarring)

Timepoint

All visits

Method of measurement

By physician

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

Each patient will receive six sessions of m3D Fractional

treatment to the whole face. The face will be thoroughly cleaned and dried before treatment. Treatment will be conducted by trained and experienced technician according to the instructions in m3D Fractional user manual. All subjects will be asked to use sunscreen with SPF 30 after each treatment session and to visit 1-week, 3- and 6-month after the last treatment session.

Category

Treatment - Devices

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

Center for Research & Training in Skin Diseases & Leprosy

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Medaria Company

Full name of responsible person

Dr.Arash Rezaei

Street address

Unit 5 ,No 57,Rajian St Gooyabadi St,Zafar St, Shariati St T

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Medaria Company

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact**

Person responsible for scientific inquiries

Contact

Name of organization / entity

Center for Research & Training in Skin Diseases & Leprosy, Tehran University of Medical Sciences

Full name of responsible person

Dr. Alireza Firooz

Position

MD, Prof. of Dermatology

Other areas of specialty/work

Street address

No. 415, Taleqani Ave.

City

Tehran

Postal code

Phone

+98 21 8897 2220

Fax

Email

firozali@tums.ac.ir

Web page address

Full name of responsible person

Dr. Leila Janani

Position

Phd in biostatistics

Other areas of specialty/work

Street address

City

Tehran

Postal code

Phone

+98 21 8896 3546

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Clinical Trial Center (CTC), Tehran University of Medical Sciences (TUMS)