Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of safety and efficacy of INOVOSENSE MESOCELL PLUS mesogel for improvement of face skin elasticity and rejuvenation

Protocol summary

Study aim
Evaluation of safety and efficacy of INOVOSENSE MESOCELL PLUS mesogel for improvement of face skin elasticity and rejuvenation

Design
An interventional, randomized, non-blinded, non-placebo, single-study, treatment-intent, phase 2 clinical trial on 20 patients.

Settings and conduct
This clinical trial will be conducted at the Razi Hospital Dermatology Clinic and the Skin Diseases and Leprosy Education and Research Center. For each person, 2 ml of MESOCELL PLUS injectable mesogel will be done in 2 sessions, 1 month apart. Then, the improvement in skin quality is assessed before the intervention and 4 weeks after the last injection based on digital before-and-after photography, measurement of skin elasticity by cutometery, and examination of the signs of skin aging, including facial lines and wrinkles, using the GAIS scale. Also, to determine the level of effectiveness, patients' photos are reviewed by two dermatologists, and patient satisfaction and possible side effects are recorded at each visit.

Participants/Inclusion and exclusion criteria
25 -60 Years women and men with visible signs of skin aging such as reduced skin elasticity and the presence of lines and wrinkles, without a history of any cosmetic procedure in the past 6 months, who have no history of autoimmune or immune deficiency diseases, epilepsy and malignant tumors, allergic diseases, granulomas associated with sarcoidosis and Osler's nodes in endocarditis, any active inflammation and infection, and no previous sensitivity to polydeoxyribonucleotides and lidocaine. No pregnant and breastfeeding.

Intervention groups
Injection of INOVOSENSE MESOCELL PLUS mesogel for improvement of face skin elasticity and rejuvenation. the products are in the 2 ml prefilled sterilized syringe containing: 40 mg polydeoxyribonucleotide 0.15% lidocaine hydrochloride

Main outcome variables
Skin elasticity level by cutometery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250308064973N1**
Registration date: **2025-03-21, 1404/01/01**
Registration timing: **retrospective**

Last update: **2025-03-21, 1404/01/01**
Update count: **0**

Registration date
2025-03-21, 1404/01/01

Registrant information

Name
mina masoudi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8243 0751

Email address
mina.masoudi@medisaara.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-10, 1403/12/20

Expected recruitment end date
2025-03-17, 1403/12/27

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of INOVOSENSE MESOCELL PLUS mesogel for improvement of face skin elasticity and rejuvenation

Public title

Evaluation of safety and efficacy of INOVOSENSE MESOCELL PLUS mesogel for improvement of face skin elasticity and rejuvenation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

25 - 60 Years women and men Signs of skin aging, such as reduced skin elasticity and the presence of lines and wrinkles on the face

Exclusion criteria:

Any cosmetic facial procedures during the last 6 months Autoimmune or immune deficiency diseases Patients with epilepsy and malignant tumors History of allergic diseases Presence of granulomas associated with sarcoidosis and Osler's nodes in endocarditis Taking medications such as NSAIDs, platelet aggregation inhibitors, anticoagulants, and immunosuppressants Active inflammation or infection Allergy to polydeoxyribonucleotides or lidocaine Pregnancy and breastfeeding

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

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 Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2025-03-04, 1403/12/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.671

Health conditions studied

1

Description of health condition studied

Skin aging

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

facial skin elasticity

Timepoint

Before the intervention and 4 weeks after the last injection

Method of measurement

cutometery

Secondary outcomes

1

Description

side effects

Timepoint

Before the intervention and 4 weeks after the last injection

Method of measurement

Based on patient's comments

2

Description

Signs of skin aging include lines and wrinkles

Timepoint

Before the intervention and 4 weeks after the last injection

Method of measurement

GAIS scale

Intervention groups

1

Description
Intervention group: INOVOSENSE MESOCELL PLUS mesogel injection for improvement of face skin elasticity and rejuvenation. the products are in the 2 ml prefilled sterilized syringe, which contains: Polydeoxyribonucleotide 40 mg, Lidocaine hydrochloride 0.25 % and Phosphate Buffer pH 7 q.s.: 2 ml

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology clinic of Razi Hospital

Full name of responsible person
Amirhooshang Ehsani

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2

Recruitment center

Name of recruitment center
Center for Research and Training in Skin Diseases And Leprosy

Full name of responsible person
Alireza firooz

Street address
No. 415, corner of Naderi (former Soheil) Street, Shahid Taleghani Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Medisa Ara Gostar Iranian company

Full name of responsible person
Masoud Saghafi

Street address
Number 21, Jooybar Alley, Shad St, Molla Sadra St, Tehran, Iran

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1435791999

Phone
+98 21 8885 6574

Email
contact@kmtmed.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Medisa Ara Gostar Iranian company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Maryam Nasimi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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