Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Preparation and characterization of lipospmal Epidermal growth factor and evaluating its efficacy on preorbital wrinkles

Protocol summary

Study aim

1. Preparation and characterization of the liposomal EGF product and its effectiveness on preorbital wrinkle, skin moisture, skin elasticity , on the surface and thickness of wrinkle and on the thickness of dermis and epidermis

Design

In this study, intervention and control are performed simultaneously in each person and is done double blind, and the patient and analyser are aware of the materials used, but unaware of which side of the face is the main intervention or control.

Settings and conduct

This intervention is examined at the skin and stem cell research center in Tehran University of Medical Sciences and it is double blind ,the patient and analyzer are unaware of which side of the face is intervention or control.

Participants/Inclusion and exclusion criteria

1-Aged between 35 to 50 years old Exclusion criteria:1-Without any restorative intervention in the face2-history of related skin diseases, autoimmune, allergies or inflammation near the site3-history of systemic diseases4-history of oral and maxillofacial infections5-positive screening tests HIV1.2Ab, HBsAg, HbcAb, HCVAb,

Intervention groups

In this study, 15 patients with the same conditions of entry are matched with skin and stem cells research center . Preorbital wrinkles on one of the side face are considered as intervention and the other site as a control. The topical cream is applied for 3 months for twice a day (morning and night). evaluating the efficacy of the cream, the biometric factors are examined once before the intervention and then 3 months later. Follow up is done until the 6th month.

Main outcome variables

Improving surface and depth eye wrinkle, Improving skin moisture , Improving skin elasticity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141007019432N7**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **prospective**

Last update: **2018-06-10, 1397/03/20**
Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Mohammadamir Amirkhani

Name of organization / entity

Skin and Stem Cell Research Center, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

empty

Scientific title
Preparation and characterization of lipospmal Epidermal growth factor and evaluating its efficacy on preorbital wrinkles

Public title
Preperation and characterization of lipospmal Epidermal growth factor and evaluating its efficacy on preorbital wrinkles

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged between 35 to 50 years old. Having a healthy face for dermatological, anatomical and sympathetic diseases Being in the wrinkle grade 2 and 3 according to the Lemperle 4 table Having psychological and social health (based on self-expression) Having knowledge And have enough time to cooperate until the end of the plan

Exclusion criteria:
Without any restorative intervention in the form of sub-sission , botox, filler, lift and surgery and etc, Having plenty of wrinkles in different areas of the skin Mental and social obsessive-compulsive disorder (based on self-declaration) history of related skin diseases, autoimmune, allergies or inflammation near the site history of prematurity cardiovascular, respiratory, diabetes, wound healing, moderate to high anemia, and other diseases that affect the process of rejuvenation history of systemic diseases history of oral and maxillofacial infections positive screening tests HIV1.2Ab, HBsAg, HbcAb, HCVAb,

Age
From **35 years** old to **50 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **3**
three samples are used for each person

Randomization (investigator's opinion)
Randomized

Randomization description
Randomisation Tool: Plumbed Envelope Two groups A, B are placed in the plumbed envelope. In Group A, the liposomal growth factor production is used on the right side and the left side of the placebo and group B the right side of the placebo and the left side of the Liposomal growth factor production is used

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double blind study , participants and analyser are unaware of the allocation of study groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences Cross Qods st , Keshavarz Blvd, Tehran ,Iran

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Province
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1417653761

Approval date
2018-01-10, 1396/10/20

Ethics committee reference number
IR.TUMS.VCR.REC.1396.4272

Health conditions studied

1

Description of health condition studied
Aging and preorbital wrinkle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Effect of liposomal epidermal growth factor production on the surface and depth of preorbital wrinkle

Timepoint
before intervention and 3 months after using

Method of measurement
The statistical population is according to the degree of wrinkles 2 and 3 in thecase of women aged between 35 and 50 years that are selected by written consent. In this study, viscosity of the skin with visioface (D1000 ck Cologne, Germany), the level and degree of wrinkle with the set (LL 650 CK Germany), the thickness and density of the skin, the dermal and epidermal with ultrasound skin scanner, DUB-TPA EOTECH, Marcoussis, France), Multiprobe , elasticity with Adapter Cutometer (Cologne, Germany) ,skin water levels by chronometer devices are examined before and after using cream for 3 months and

the numbers will be compared. All statistical analyses will be done in SPSS software

Secondary outcomes

1

Description
Effect of liposomal epidermal growth factor production on moisture ,elasticity and dermal -epidermal thickness,
Timepoint
before intervention and 3 months after using
Method of measurement
The statistical population is according to the degree of wrinkles 2 and 3 in thecase of women aged between 35 and 50 years that are selected by written consent. In this study, viscosity of the skin with visioface (D1000 ck Cologne, Germany), the level and degree of wrinkle with the set (LL 650 CK Germany), the thickness and density of the skin, the dermal and epidermal with ultrasound skin scanner, DUB-TPA EOTECH, Marcoussis, France), Multiprobe , elasticity with Adapter Cutometer (Cologne, Germany) ,skin water levels by chronometer devices are examined before and after using cream for 3 months and the numbers will be compared. All statistical analyses will be done in SPSS software

Intervention groups

1

Description
Intervention group:In this study, 15 patients with the same conditions of entry are matched with t skin and stem cells research center . wrinkles around the eye on one of the side face are considered as intervention and the other site as a control. The topical cream application is used for 3 months for twice a day (morning and night). evaluating the efficacy of the cream, by the biometric factors are examined once before the intervention and then 3 months later. Fallow up is done until the 6th month.
Category
Treatment - Other

2

Description
Control group:The control group in this study is the same as participating in intervention, one side of the face being considered as a control.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin & Stem Cell Research Center in Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Amir Amirkhani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Deputy 's educational in skin and stem cell research centre of Tehran University Medical Sciences
Grant code / Reference number
12370022
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammadamir Amirkhani

Position
Consultant

Latest degree
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Other areas of specialty/work
skin and stem cell

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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
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
Undecided - It is not yet known if there will be 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