

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Efficacy and safety of human dermal fibroblasts cultured in clinical-grade large scale cultured system compared to placebo in treatment of nasolabial folds : A randomized, placebo controlled phase 3, parallel, double blinded clinical trial

Protocol summary

Study aim

To determine efficacy and safety of cultured fibroblasts in the treatment of nasolabial folds

Design

phase 3, 60 nasolabial wrinkle patients. Block randomization, placebo controlled, parallel

Settings and conduct

Study site: Royan institute, Tehran, Iran. After including the eligible patients and receiving their written consent, wrinkle assessment are evaluated by the physician and the patient. 2D imaging and ultrasonographic findings are recorded and the thickness of epiderm and derm plus dermal density will be measured. The patients and outcome assessors are blinded to the interventions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 30 to 60 years, nasolabial folds, WAS 3to5, length of wrinkle line 12 to 15 cm, written consent to participate/Exclusion criteria: chronic disease, pregnancy, lactation, cancer, HIV, HCV or HBV positive, history of cell therapy, skin interventions in the last 6 months, history of organ transplantation or blood transfusion, immunosuppressive or cytotoxic use in the last 6 months, history of skin mass or benign skin disease, history of anticoagulants use, mesotherapy or skin surgery, injection of permanent fillers, injection of botulinum before the end of efficacy time, HSV history, active infection at the site, heavy diet for weight change, collagen or fibroblast producing diseases, allergy to bovine products, allergy to streptomycin or penicillin, using retinoid drugs during the last 6 months, hypo/hyperthyroidism, history of severe mental problems

Intervention groups

control group: placebo 0.1 ml/cm in each injection
Intervention group: Fibroblast 20millions of cells/ml in volume of 0.1ml/cm in each injection

Main outcome variables

remission rate (with at least 2 units change in WAS)
based on physician's evaluation and images comparison before and 9 months after the injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003200N5**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **prospective**

Last update: **2018-10-25, 1397/08/03**

Update count: **1**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Kazem Heidari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy and safety of human dermal fibroblasts cultured in clinical-grade large scale cultured system compared to placebo in treatment of nasolabial folds : A randomized, placebo controlled phase 3, parallel, double blinded clinical trial

Public title
Effects of cultured fibroblast on reducing nasolabial folds

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 30-60 years Having nasolabial folds Wrinkle Assessment Scale between 3 to 5 Nasolabial fold line length between 12-15 cm Written consent to participate and willingness to attend in regular treatment / follow up visits
Exclusion criteria:
 Having a known chronic disease pregnancy or plan to be pregnant during the next 5 years Lactation history of cancer or chemotherapy Having viral disease: HIV, HBV or HCV History of cell therapy History of lipotransfer at the nasolabial region UV, laser or PRP interventions in the last 6 months History of organ transplantation or blood transfusion History of allergy to anesthetic drugs History of using immunosuppressive or cytotoxic drugs in the last 6 months History of Skin mass or benign skin diseases History of anticoagulant use Mesotherapy or skin surgery Injection of permanent fillers Injection of botulinum or fillers before the end of efficacy time HSV history Active infection at the injection site Diabetes Being under heavy diet for weigh loss or weight gain Collagen of fibroblast producing diseases like marfan syndrome or epidermolysis bullosa History of allergy to bovine products History of allergy to streptomycin or penicillin Using retinoid drugs during the last 6 months Uncontrolled hypothyroidism or hyperthyroidism History of severe mental problems like depression, anxiety disorders or bipolar disorders

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization list will be generated using online source: <https://www.sealedenvelope.com>. Block randomization with block size 4 results in generation of 15 blocks. After the randomization list generation, every patient will be assigned a unique identification code. All the staff conducting the study will be blinded to randomization list. Opaque sealed consecutively numbered envelopes will be used for the allocation concealment process. Each envelope will be opened after assuring eligibility of the participant and giving written signed consent form.

Blinding (investigator's opinion)
Double blinded

Blinding description
patients will receive similar 100 units, gauge 30 syringes in both groups. Those who conduct the injections are different from those who conduct the examinations and patients' assessments. The packages of investigational products will be labelled by unique codes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Vice chancellor for research, Tehran University of Medical Sciences
Street address
 Qods street
City
 Tehran
Province
 Tehran
Postal code
 1346694133

Approval date
2018-04-18, 1397/01/29

Ethics committee reference number
IR.TUMS.VCR.REC.1397.091

Health conditions studied

1

Description of health condition studied
Nasolabial folds

ICD-10 code
L98.8

ICD-10 code description
Other specified disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description

Remission rate

Timepoint

Before and nine months after injection

Method of measurement

Wrinkle assessment scale

Secondary outcomes

1

Description

Wrinkle Assessment Scale

Timepoint

Before and weeks 20, 32 and 44 after injection

Method of measurement

score 1 to 5 regarding image comparisons before and after injection

2

Description

Subject Self-assessment of wrinkle

Timepoint

Before and weeks 20, 32 and 44 after injection

Method of measurement

Subject Self-assessment Scale of wrinkle: score -2 to +2

3

Description

Length, depth and volume of wrinkle

Timepoint

Before and weeks 20, 32 and 44 after injection

Method of measurement

Two dimensional imaging by VisioFace

4

Description

Thickness of epiderm and derm and dermal density

Timepoint

Before and weeks 20, 32 and 44 after injection

Method of measurement

Ultrasonographic findings

5

Description

Adverse events

Timepoint

Every time happens

Method of measurement

From adverse events list

Intervention groups

1

Description

Control group: Placebo injection 0.1 ml/cm in each injection: three injections in 4 consecutive weeks

Category

Placebo

2

Description

Intervention group: Fibroblast injection 20 millions of cells in 0.1 ml/cm in each injection: three injections in 4 consecutive weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Saeed Shafieyan

Street address

Royan Ave., East Hafez St., Banihashem St

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sshafiiyan@yahoo.com

Web page address

<http://www.royaninstitute.org/cmsen/index.php>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barkat pharmaceutical group

Full name of responsible person

Nasser Aghdami

Street address

No. 11, 5th Alley, Bucharest Ave., Argentina Sq

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Email

info@bpharmed.com

Web page address

http://www.bpharmed.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barkat pharmaceutical group

Proportion provided by this source

50

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

Royan Institute for Stem Cell Biology and Technology

Full name of responsible person

Saeid Shafieian

Position

Scientific Head of Skin Cell Research and Therapy Center, Regenerative Medicine Department

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Name of organization / entity

Royan Institute for Stem Cell Biology and Technology

Full name of responsible person

Saeid Shafieian

Position

Scientific Head of Skin Cell Research and Therapy Center, Regenerative Medicine Department

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Kazem Heidari

Position

Non faculty member PhD

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

No - There is not 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