

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparative Efficacy Evaluation of a Topical Cream (DEMULcent™) Containing Arnica and Rosemary Extracts with Placebo on Filler-Injected Patients Bruise: A randomized Double-blind Control Trial

Protocol summary

Study aim

Comparison of the length of the bruising period between the intervention and the placebo groups

Design

A parallel double blind on 80 nasolabial filler-injected patients having ecchymosis clinical trial, randomized with blocks of four.

Settings and conduct

After obtaining approval from the ethics committee and obtaining the clinical trial code, the study entered the implementation stage and was carried out at Razi Dermatology Hospital under the supervision of 2 professors of Tehran University of Medical Sciences with the help of a nurse and a statistical consultant.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes receiving nasolabial filler injection at Razi Hospital (having bruises caused by the injection) and entry age is 18 to 65 years old. Exclusion criteria includes pregnancy, breastfeeding, taking aspirin or other anticoagulants. Exiting criteria includes pregnancy (or having plan for pregnancy) and not assigning inform consent.

Intervention groups

-Intervention group (3 times/day for 14 days). -Placebo group (3 times/day for 14 days).

Main outcome variables

Severity of bruising based on surface area The stage (age) of bruises between intervention cream and Placebo at each stage The bruise healing period based on the day of the intervention

General information

Reason for update

Acronym

DABCET-F

IRCT registration information

IRCT registration number: **IRCT20141209020250N7**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Narges Ghandi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5561 8989

Email address

nghandi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Efficacy Evaluation of a Topical Cream (DEMULcent™) Containing Arnica and Rosemary Extracts

with Placebo on Filler-Injected Patients Bruise: A randomized Double-blind Control Trial

Public title

Evaluation of DEMU La' farrerr Topical Cream Effect on Bruises Caused by Filler Injection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals Receiving Nasolabial Filler Injection or Facial Botox at Razi Hospital (With Bruises Caused by Filler Injection in the Face Area) Age between 18 and 65

Exclusion criteria:

Pregnancy Possibility or Having Plan for Pregnancy in the Next 3 Months Lactation Taking Aspirin and Other Anticoagulant Medicines Unwillingness to Participating in the Trial

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In each of the two intervention groups, the participants are divided into randomized blocks based on the randomization process after confirming that they have the conditions to enter the project. Randomization in this way has been done with the help of 4 random blocks. Each of the houses is A or B, and when the patients go to the hospital, depending on the prepared envelopes, where the patient's number and the type of intervention A or B are marked on each envelope and the type of intervention A or B is marked inside the envelope, from the box containing product A Or it is given from the box containing product B. In this study, 6 types of blocks for each block of 4 can be expected, with two placebo and two intervention volunteers in each group. Each block model is marked with a number from one to six, and for each block, a random number is taken from 1 to 6 with the help of Microsoft Excel, which determines the sequence of receiving cream and placebo for each person, and the total sequence . And the order of 20 blocks of this study is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Initially, patients are included in the process of research and are added to the plan if they wish. For more familiarity and assurance, an informed consent form is given to them. After entering the plan and seeing a

bruise at the place of filler injection, in the first visit, they will be given an envelope containing the representative number of each person based on the appointment and the number that will be assigned to them. There is a sheet in each of these envelopes, some of which are sheet A and others are sheet B. Depending on which sheet the patient's envelope contains, a cream from box A or a cream from box B will be given from the two boxes available to the nurse of the plan. A double-blind study means that all creams and boxes A or B are blinded for the research doctors of the plan, the executive director, the associate nurse, the patients, and all the hospital staff. Also, the formulation company delivers the intervention cream and placebo in the form of two separate boxes, and the labeling of which cream A contains intervention cream (demo) or placebo and B is done only by and with the knowledge of the plan's statistical consultant. And only he is aware of the grouping, but he does not participate or interfere in the process of implementing the plan. The method of randomization is based on the method that was explained. All the creams with white tube and no explanation except that they are A or B. And in the process of formulating both, all facilities are used by the patient to match the color, smell, consistency, appearance and other tangible characteristics so that the type of cream available in each group A and B is not predictable.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of School of Medicine- Tehran University of Medical Sciences

Street address

Keshavarz Blvd., Corner of Qods St., Central Organization of Tehran University of Medical Sciences, 6th floor: Room 604 (Research and Technology Affairs Experts and Ethics Committee)

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-08-06, 1402/05/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.257

Health conditions studied

1

Description of health condition studied

Bruising Caused by Nasolabial Filler Injection

ICD-10 code

R23.3

ICD-10 code description

Spontaneous ecchymoses (Petechiae). Excl: ecchymoses in fetus and newborn, purpura.

Primary outcomes

1

Description

Bruise Intensity by the Surface Area

Timepoint

Days 1, 2, 3, 4, 5, 7, 10 and 14

Method of measurement

Total bruised area measurement

2

Description

The stage (age) of bruises

Timepoint

Days 1, 2, 3, 4, 5, 7, 10 and 14

Method of measurement

Spot Color by Colorimetric Scale NNDV No. 2

3

Description

Bruise Control Time Period

Timepoint

Length of treatment period (14 days)

Method of measurement

Clinical examination and review of images taken from the position

Secondary outcomes

1

Description

Pain feeling in the spot

Timepoint

Days 1, 2, 3, 4, 5, 7, 10 and 14

Method of measurement

The numeric rating scale (NRS)

2

Description

Side Effects (Hypersensitivity or any other side effects not related to other treatments and medicines received by the patient)

Timepoint

Length of treatment period (14 days)

Method of measurement

Patient statements during examinations and other times

3

Description

Volume of filler injected to the site by ml

Timepoint

Day 0 (Filler injection)

Method of measurement

ml of filler injected

Intervention groups

1

Description

Intervention group: DEMULcent Cream Containing Arnica, Rosemary, Chamomile and... Extracts La' farrerr in a white and unspecified Tube/Used for 14 days, Every 8 Hours at the Filler Injection Site and Around.

Category

Treatment - Drugs

2

Description

Control group: Placebo Cream Containing Other Ingredients Found in DEMULcent La' farrerr Cream in a White and Unspecified Tube with the Same Smell and Viscosity/Used for 14 days, every 8 hours at the filler injection site and around of it

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Specialty Skin Hospital

Full name of responsible person

Dr.Narges Ghandi

Street address

Razi DdEnd., Vahdate-Eslami St., Vahdate-Eslami Sq., Tehran Town

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5561 8989

Email

nghandi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Narges Ghandi
Street address
Razi DdEnd., Vahdate-Eslami St., Vahdate-Eslami Sq.,
Tehran Town
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5561 8989
Fax
+98 21 5515 5050
Email
nghandi@tums.ac.ir
Grant name
Grant code / Reference number
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
1
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

2

Sponsor

Name of organization / entity
PergasTeb Ltd.
Full name of responsible person
Dr. Nasim Karimi
Street address
Tehran-Jordan St.-West Saba Blvd.-P.36
City
Tehran
Province
Tehran
Postal code
1917763888
Phone
+98 21 7236 2000
Email
n.karimi@lafarrerr.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

PergasTeb Ltd.
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
Danial Mehrali
Position
Pharm.D Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Pharmacy Faculty., Tehran University of Medical
Sciences., 16 Azar St., Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 64120
Email
danielmehrali@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Narges Ghandi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
District 12, vahdate eslami square, Razi hospital
City
Tehran
Province
Tehran
Postal code
1199663911

Phone

+98 21 5563 0553

Email

nghandi@tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr.Narges Ghandi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Razi DdEnd., Vahdate-Eslami St., Vahdate-Eslami Sq.,
Tehran Town

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5561 8989

Fax

+98 21 5515 5050

Email

nghandi@tums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Related information aren't published publicly, but will be available anytime.

Study Protocol

No - There is not 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