# 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

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Iran (Islamic Republic of)

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**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
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## Sponsors / Funding sources

### 1

**Sponsor**

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**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
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Tehran-Jordan St.-West Saba Blvd.-P.36
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**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
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## 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