

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of chitosan gel containing Moringa Olifra leaf powder on surgical wound healing Breast cosmetic surgery

Protocol summary

Study aim

Assessment of the effect of gel containing Moringa Oleifera leaf powder on wound healing of breast cosmetic surgeries

Design

Phase 1 clinical trials are performed on 30 patients. Randomization uses the rand function of Excel software. According to the instructions on the random envelopes, the gels are labeled with two different colors, neither the researchers nor the participants know which breast received which gel.

Settings and conduct

First, water-alcoholic extract is taken from the dry powder of Moringa in suitable laboratory conditions and then it is concentrated. Then, the base gel is made using chitosan polymer powder and 3% concentration of gels is made using the concentrated extract of Moringa Olifra plant. 30 female patients are selected selectively. The duration of treatment is twice a day for 14 days and patients follow up for up to 3 months to control the wound healing process and scar formation. Then, at the end of the second week and the third month, the patients were evaluated for wound healing process and Vancouver criteria by two clinical assistants. Then it was analyzed using data collection form. The participant, The researcher, the analyst don't know which side received which gel

Participants/Inclusion and exclusion criteria

patients referred for aesthetic breast surgery
Inclusion Criteria - Age 18 to 70 years - Gaining informed consent -
Exclusion Criteria: -Chemotherapy - Drug abuse - Systemic diseases - Receiving corticosteroid drugs -Drug addiction -Cancer - Taking any hormonal medication - Smoking

Intervention groups

The lateral side of a breast is rubbed with gel Moringa plant extract The medial side of the same breast that has not been rubbed anything The lateral side of the breast is rubbed against the placebo gel The medial side of the

same breast that has not been rubbed anything

Main outcome variables

Flexibility Height Pigments Vascularity

General information

Reason for update

Acronym

Moringa Oleifera - wound healing MO-WH

IRCT registration information

IRCT registration number: **IRCT20211206053294N1**

Registration date: **2021-12-25, 1400/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-25, 1400/10/04**

Update count: **0**

Registration date

2021-12-25, 1400/10/04

Registrant information

Name

Shirin Haji Mazdarani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

sh.mazdarani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chitosan gel containing Moringa Olifra leaf powder on surgical wound healing Breast cosmetic surgery

Public title

The effect of gel containing Moringa Olifra on surgical wound healing Breast cosmetic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 70 Gain conscious satisfaction
Female patients referred for cosmetic breast surgery including prosthesis and reduction mammoplasty

Exclusion criteria:

Chemotherapy Drug abuse Systemic diseases Get corticosteroids medication Drug addiction Cancer Take any hormonal medication Smoking

AgeFrom **18 years** old to **70 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description

The patient in the study knows that if he receives two different jellies on the right and left side of the breast, their effect will be compared, but he does not know which side contains the Moringa plant and which side he has received Placebo. The researcher does not know which Moringa wound and which placebo wound he received when scoring the wounds. The analyst is unaware of the allocation of wounds to the group receiving Moringa gel and the group receiving placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of School of Medicine-Shahid Beheshti University of Medical Science

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.SBMU.MSP.REC.1398.1004

Health conditions studied**1****Description of health condition studied**

Wound healing

ICD-10 code

T81.31

ICD-10 code description

Disruption of external operation (surgical) wound, not elsewhere classified

Primary outcomes**1****Description**

Vascularity

Timepoint

3 month

Method of measurement

Visual Analogus Scale

2**Description**

Pigmentation

Timepoint

3 Month

Method of measurement

Visual Analogus Scale

3**Description**

Pliability

Timepoint

3 Month
Method of measurement
Touch

4

Description

Height

Timepoint

3 Month

Method of measurement

Ruler

Secondary outcomes

empty

Intervention groups

1

Description

The wound intervention group received chitosan-based gel containing 3% Moringa Olifera leaf powder extract, made in a traditional medicine laboratory, 24 hours after surgery, twice a day for two weeks

Category

Treatment - Drugs

2

Description

Control group: The wound intervention group received chitosan-based gel without extract of 3% Moringa Olifera leaf powder, made in a traditional medicine laboratory, 24 hours after the operation, twice a day for two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Panzdah-e Khordad Hospital

Full name of responsible person

Shirin Hajimazdarani

Street address

Azodi street- Karimkhan Street

City

Teheran

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Postal code

1598764514

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+98 21 8894 3434

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Email

shekayat@sbmu.ac.ir

Web page address
<https://pkmc.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shirin Haji Mazdarani

Position

Rezident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

تمام اطلاعات در قالب یک مقاله شش ماه پس از اتمام کار در اختیار متقاضیان قرار خواهد گرفت

When the data will become available and for how long

Access started from September 2022

To whom data/document is available

All data will be made available to researchers working in the institutions of scientific and academic universities

Under which criteria data/document could be used

students

From where data/document is obtainable

Applicants can email Shirin Haji Mazdarani to sh.mazdarani@yahoo.com or 09126063272

What processes are involved for a request to access data/document

Participants can send all their questions via email. All information will be provided to respondents in the form of a report via email within one month

Comments