

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The Evaluation of the Effect of Sildenafil Topical Cream with dexpanthenol on the Healing Process of Scar Caused by Neck Surgeries: A Double Blinded Randomized Controlled Trial

Protocol summary

Study aim

A comparative study of the effect of topical sildenafil cream with dexpanthenol on the healing process of scars caused by neck surgeries

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, on 46 patients. Randomization was done with SAS software version 9.

Settings and conduct

The study will be conducted in Amir al-Mominin Hospital in Rasht. The study will be conducted in two groups of intervention and control. The participant and the researcher will be blind.

Participants/Inclusion and exclusion criteria

-Patients over 18 years of age who have neck wounds caused by surgery and refer to Amir al-Momenin Hospital in Rasht. - No previous allergy to products containing sildenafil - Not using other drugs that are effective in wound healing - Absence of diseases that interfere with wound healing (chronic systemic diseases of the heart, kidneys, lungs, coagulation disorder, immune deficiency, connective tissue disorder, diabetes, anemia, hemophilia, and malnutrition) - No history of injury or previous surgery and visible lesions in the neck area

Intervention groups

After the surgery and the disappearance of the wound condition and the infection of the surgical site, the first group receives topical sildenafil 10% cream together with dexpanthenol 3 times a day and the second group receives topical dexpanthenol cream 3 times a day for a period of three months. Patients are visited weekly and the wound healing process is measured.

Main outcome variables

In order to evaluate the healing process of the wound in this study, the SCAR scale was used: scar spread; erythema; dyspigmentation (includes hyperpigmentation and hypopigmentation); track marks or suture marks;

hypertrophy/atrophy; overall impression and the patient's pain and itching are the measured variables.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054879N9**

Registration date: **2023-11-20, 1402/08/29**

Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**

Update count: **0**

Registration date

2023-11-20, 1402/08/29

Registrant information

Name

maryam shahrokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9026

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Evaluation of the Effect of Sildenafil Topical Cream with dexpanthenol on the Healing Process of Scar Caused by Neck Surgeries: A Double Blinded Randomized Controlled Trial

Public title
Investigating the effect of Sildenafil topical cream compared to Dexpanthenol cream on neck wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
-Patients over 18 years of age who have neck wounds caused by surgery and refer to Amir al-Momenin Hospital in Rasht.- No previous allergy to products containing sildenafil- Not using other drugs that are effective in wound healing- Absence of diseases that interfere with wound healing (chronic systemic diseases of the heart, kidneys, lungs, coagulation disorder, immune deficiency, connective tissue disorder, diabetes, anemia, hemophilia, and malnutrition)- No history of injury or previous surgery and visible lesions in the neck area
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
The 4 permutation block randomization method was used to randomize patients into two groups. Given that Group A is the intervention group and Group B is the control group. Randomization was done with SAS software version 9. For allocation concealment, opaque-sealed envelopes will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted in a double-blind manner, so that two topical creams containing sildenafil and dexpanthenol will be prepared for the treatment and control groups in the Faculty of Pharmacy and delivered to the therapist in similar containers with A and B labels. The type of treatments will be placed inside a sealed envelope delivered to the statistical analyst, and the therapist and the patient will not know the type of

treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Deputy of research and technology, In front of 17 shahrivar hospital, Shaid siadati street, Namjoo street, Rasht
City
Rasht
Province
Guilan
Postal code
4193713111

Approval date
2023-10-18, 1402/07/26

Ethics committee reference number
IR.GUMS.REC.1402.373

Health conditions studied

1

Description of health condition studied
Scar caused by neck surgery

ICD-10 code
L90.5

ICD-10 code description
Scar conditions and fibrosis of skin

Primary outcomes

1

Description
Scar spread

Timepoint
Scar spread will be measured at the beginning of the study and then weekly for 3 months

Method of measurement
Based on the observation of the researcher

Secondary outcomes

1

Description

Erythema

Timepoint

Erythema will be measured at the beginning of the study and then weekly for 3 months.

Method of measurement

Based on the observation of the researcher

Intervention groups

1

Description

Intervention group: Receive Sildenafil 5% topical cream three times a day.

Category

Treatment - Drugs

2

Description

Control group: Receiving dexpanthenol 5% topical cream 3 times a day from Pharmachemy pharmaceutical company for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al-Momenin Hospital

Full name of responsible person

Ali Faghih Habibi

Street address

Amir- al Momenin Educational Remedial & Research Center, 17th Shahrivar Street, Dr. Heshmat Square, Imam Khomeini Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Maryam Shahrokhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

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Full name of responsible person

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Pharmacy Student

Latest degree

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Medical Pharmacy

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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

Preservation of patients' privacy and compliance with ethical principles

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

No - There is not 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

The results of the study will be available to everyone, specific information will be available only to the treatment staff. To protect the patient's privacy, the patient's information will be protected by the researcher.

When the data will become available and for how long

There is currently no plan to publish the data, but if published, it will be 6 months after the results are published.

To whom data/document is available

Researchers working in this field, Otolaryngologists and scientists with qualifications

Under which criteria data/document could be used

Physicians and researchers will have the right to request, there are restrictions on patient privacy and medical ethics

From where data/document is obtainable

17 Shahrivar Rasht Hospital, Dr. Maryam Shahrokhi; Gilan Faculty of Pharmacy, Parmida Khorrami, Medical Sciences

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

Refer to the 17 Shahrivar Hospital in Rasht and sign the application form, then meet with the project researcher and review the client's request - consult with the Medical Ethics Committee, then provide documentation

Comments