Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
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+98 13 3336 9026
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mshahrokhi@gums.ac.ir

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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In front of 17 shahrivar Hospital, Shahid Siadati Street, Namjoo Street
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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
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Person responsible for updating data

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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