Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the effects of Hypericum Perforatum and Dexpanthenol topical cream on the healing process of scar caused by neck surgeries

Protocol summary

Study aim

A comparative study of the effect of Hypericum Perforatum and Dexpanthenol topical cream on the healing process of scar caused by neck surgeries

Design

This a controlled, paralleled, double-blind, randomized, clinical trial on 48 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

Inclusion criteria: Neck surgery After suture removal Obtaining informed consent Exclusion criteria: Previous sensitivity to products containing Hypericum Perforatom Receiving other drugs effective on wound healing Suffering from diseases that interfere with wound healing (chronic systemic diseases of the heart, kidney, lung, coagulation disorder, immune deficiency, connective tissue disorder, diabetes, anemia, hemophilia, and malnutrition) Having a history of previous injury or surgery and visible lesions in the neck area

Intervention groups

After surgery and suture removal, the first group receives Hypericum Perforatom topical cream 3 times a day and the second group receives Dexpanthenol cream 3 times a day for three months. During three months, the patients will be visited weekly and the healing process of the wound will be 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: **IRCT20220516054879N6**
Registration date: **2023-07-03, 1402/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-03, 1402/04/12**
Update count: **0**

Registration date

2023-07-03, 1402/04/12

Registrant information

Name

maryam shahrokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9026

Email address

mshahrokhi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-03, 1402/03/13

Expected recruitment end date

2023-10-05, 1402/07/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A comparative study of the effects of Hypericum Perforatum and Dexpanthenol topical cream on the healing process of scar caused by neck surgeries

Public title
The effects of Hypericum Perforatum and Dexpanthenol topical cream on the healing process of scar

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with neck wounds caused by surgery After removing the stitches obtaining informed consent

Exclusion criteria:
Previous sensitivity to products containing Hypericum Perforatom Receiving other drugs effective on wound healing Suffering from diseases that interfere with wound healing (chronic systemic diseases of the heart, kidney, lung, coagulation disorder, immune deficiency, connective tissue disorder, diabetes, anemia, hemophilia, and malnutrition) Having a history of previous injury or surgery and visible lesions in the neck area

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

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 is a double-blind study. Comparison of color and smell between Hypericum and Dexpanthenol creams will be done using allowed color and essential oil. The type of treatment will be placed inside a sealed envelope and delivered to the nurse and statistical analyst. The researcher and the participant will be blind.

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
2023-05-03, 1402/02/13

Ethics committee reference number
IR.GUMS.REC.1402.058

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

2

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

3

Description
Dyspigmentation
Timepoint
Dyspigmentation 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

4

Description
Track marks or suture marks
Timepoint
Track marks or suture marks 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

5

Description
Hypertrophy/atrophy
Timepoint
Hypertrophy/atrophy 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

6

Description
Overall impression
Timepoint
Overall impression 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

7

Description
Pain
Timepoint
Pain will be measured at the beginning of the study and then weekly for 3 months.
Method of measurement
Based on questions from the patient

8

Description
Itch
Timepoint
Itch will be measured at the beginning of the study and then weekly for 3 months.
Method of measurement
Based on questions from the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving 3 times a day topical cream formulation of Hypericum perforatum plant with 70% ethanolic extract with 2% concentration of total extract for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Receiving 3 times a day Dexpanthenol 5% topical cream from Raha Pharmaceutical Company for 3 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
City
Rasht
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4139637459
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Email
amiralmomenin@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
In front of 17 shahrivar Hospital, Shahid Siadati Street, Namjoo Street
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Rasht
Province
Guilan

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4193713111
Phone
+98 13 3333 6394
Email
research@gums.ac.ir

Grant name

Grant code / Reference number

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

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 inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Fatemeh Naghibi
Position
Pharmacy Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Unit 4, No.1174, Yousefi Alley, Namjoo Street
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Province
Guilan
Postal code
4144664145
Phone
+98 911 865 1643
Email
fatemeh.naghibi77@gmail.com

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
Patient privacy and 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

Dr. Maryam Shahrokhi, 17 Shahrivar Hospital, Rasht; Fatemeh Naghibi, School of Pharmacy guilan university of meical science

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