# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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
**Province**
Guilan
**Postal code**
4139637459
**Phone**
+98 13 3323 8307
**Fax**
**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
**City**
Rasht
**Province**
Guilan

**Postal code**
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
**Street address**
17shahrivar Hospital, Shahid Siadati Street, Namjoo Street
**City**
Rasht
**Province**
Guilan
**Postal code**
414465379
**Phone**
+98 13 3336 9019
**Email**
shahrokhi.mail85@gmail.com

## Person responsible for scientific 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
**Street address**
17shahrivar Hospital, Shahid Siadati Street, Namjoo Street
**City**
Rasht
**Province**
Guilan
**Postal code**
4144654379
**Phone**
+98 13 3336 9019
**Email**
shahrokhi.mail85@gmail.com

## 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
**Street address**
Unit 4, No.1174, Yousefi Alley, Namjoo Street
**City**
Rasht
**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**