Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of stop scar cream on the prevention of scar formation in sutured wounds caused by biopsy

Protocol summary

Study aim
Determining the effect of Scar Stop cream on the prevention of scar formation (hypertrophic, keloid and atrophic) in sutured wounds caused by biopsy for three weeks.

Design
It is done randomly and using the method of blocks with size of 2. This study is single blind and has two intervention and comparison groups. Also, the considered sample size is 25 people under drug treatment in wound caused by biopsy and 25 people under common treatment in wound caused by biopsy.

Settings and conduct
It will be done in Razi Hospital and Dermatology and Leprosy Research Center of Tehran, and the samples of the present study are people with biopsy wounds. The cases are people with wounds caused by punch biopsy, and Scar Stop cream is made by a pharmacist, then the cream and the common treatment, which is considered zinc oxide here, are coded as (B, A). Those who use it will not know whether they are using zinc oxide or cream, on the contrary, the people who give medicine know the type of ingredients and cream.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. People aged 18-60 years 2. Wound caused by punch biopsy 3. Willingness to participate in the study Exclusion criteria: 1. Having diabetes and lupus . Patients with various malignancies 3. Patients with a history of radiotherapy 4. Use of corticosteroids for more than a week 5. Unwillingness to continue participating in the study for any reason

Intervention groups
The intervention and comparison groups are both randomly selected from patients undergoing biopsy, and the intervention group is treated with the desired cream (Scar Stop) and the comparison group is treated with zinc oxide ointment.

Main outcome variables
The process of scar formation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220730055580N1**
Registration date: **2023-01-17, 1401/10/27**
Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**
Update count: **0**

Registration date
2023-01-17, 1401/10/27

Registrant information

Name
mohamad parsa tabar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 4238 8491

Email address
mohamadparsatbar@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-14, 1401/05/23

Expected recruitment end date
2022-12-14, 1401/09/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of stop scar cream on the prevention of scar formation in sutured wounds caused by biopsy

Public title

The effect of herbal vitamin cream on preventing scarring

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1. People aged 18-60 years 2.Not suffering from acute or chronic diseases (any diseases such as diabetes, etc.) 3. No history of active skin disease 4. Insensitivity to herbal medicines 5. Not using drugs that interfere with wound healing, such as corticosteroids 6. No history of diseases interfering with wound healing 7. Willingness to participate in the study

Exclusion criteria:

1. Patients with oozing wounds with tissue loss . Malnourished patients 3. Patients with various malignancies 4. Patients with a history of radiotherapy 5. Use of corticosteroids for more than a week 6. Non-cooperation in intervention such as non-cooperation in regular and timely use of cream . Unwillingness to continue participating in the study for any reason

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomized clinical trial, the randomized block method is used in which we use double blocks (there are equal numbers of each group in each group), the desired cases of people with wounds caused by punch biopsy (with diameter 3 mm) using the online tool Sealed Envelope Ltd, random blocks and the order of allocation of treatment groups have been determined. Scarstop cream with A and zinc oxide ointment with B are shown in blocks. The samples will be assigned to two treatment groups according to the order of entering the center, if they have expressed their consent to enter the study in writing and the treatments based on the list predetermined by the online tool. The intended intervention is the use of Scar Stop cream, which is made by a clinical pharmacist. In this study, the participants are divided into two intervention and control groups. Scar Top cream is used for the intervention group and zinc oxide ointment is used for the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

This research will be conducted in a single blind (assessor blind) in such a way that the medicine packaging containers are unnamed and have the same shape, color and appearance and are named as A, B, And the people who evaluate the scar after the wound, as well as the patients, will not know whether they are using zinc oxide or cream, on the contrary, the people who give medicine know the type of ingredients and cream.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Faculty of Nursing and Midwifery and Rehabilitation Faculty of Medical Sciences

Street address

Tawheed Square, Dr. Mirkhani St. (East Nusrat)

City

tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.TUMS.FNM.REC.1401.047

Health conditions studied

1

Description of health condition studied

Scars caused by wounds (keloid, hypertrophic, atrophic)

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Vascularity

Timepoint

On the day of the intervention and the day of the end of the study

Method of measurement

Patient and Observer Scar Assessment Scale

2

Description
pigment:
Timepoint
On the day of the intervention and the day of the end of the study
Method of measurement
POSAS scale

3

Description
thickness
Timepoint
On the day of the intervention and the day of the end of the study
Method of measurement
POSAS scale

4

Description
flexibility
Timepoint
On the day of the intervention and the day of the end of the study
Method of measurement
POSAS scale

5

Description
surface area
Timepoint
On the day of the intervention and the day of the end of the study
Method of measurement
POSAS scale

Secondary outcomes

empty

Intervention groups

1

Description
Scar Top cream (made by a clinical pharmacist in the laboratory) is used for the intervention group and zinc oxide ointment is used for the control group. Then the common cream and treatment are coded as (B, A). Intervention group: At the beginning of the intervention, the wound site is completely washed and disinfected with normal saline, and after that, the desired site is completely dried using sterile gas. In the next step, a layer of the produced cream is placed on the wound site of the intervention group samples (for 2 times a day) and there is no need to massage and cover the wound surface. All cases are taught to the cases in a training session) and this work will be done every day for 3 weeks. 3 weeks and 6 weeks after the start of scar treatment, the lesion site is evaluated by a person who is not aware of the type of treatment. . Evaluation methods include: photography and POSAS criteria
Category
Treatment - Drugs

2

Description
Control group: At the beginning of the intervention, the wound site is completely washed with normal saline and disinfected, and after that, the desired site is completely dried using sterile gas. In the next step, on the wound site of the control group samples (under common treatment), a layer of zinc oxide (Raha Pharmaceutical Company) is placed on the wound site (and it is placed on 2 times a day as well There is no need to massage and cover the wound surface and this will be done every day for 3 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Skin Hospital
Full name of responsible person
mohamad parsa tabar
Street address
Tehran-Vahdat-Islami Street-Vahdat-Islami Square-Razi Dead End-Razi Skin Specialist Hospital
City
tehran
Province
Tehran
Postal code
1999663911
Phone
+98 21 5563 0553
Email
razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fatuhi
Street address
Keshavarz Blvd. Qods Street. University Central Organization. 6th floor of Research and Technology Vice-Chancellor
City
tehran
Province
Tehran

Postal code
1417653761
Phone
+98 21 3686 8163
Email
afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
mohamad parsa tabar
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Safi Abad, Bahnar St
City
dezfull
Province
Khouzestan
Postal code
6463164467
Phone
+98 61 4238 8491
Email
mohamadparsatbar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
mohamad parsa tabar
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Safi Abad, Bahnar St
City
dezfull
Province
Khouzestan
Postal code
6463164467
Phone
+98 61 4238 8491
Email
mohamadparsatbar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
mohamad parsa tabar
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Nursery
Street address
Safi Abad, Bahnar St
City
dezfull
Province
Khouzestan
Postal code
6463164467
Phone
+98 61 4238 8491
Email
mohamadparsatbar@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available