Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of oral and topical Cicaglocal drug on wound healing in patients after micrographically oriented histographic surgery (Mohs surgery)

Protocol summary

Study aim
Determining and comparing the average score of wound healing on days 7 and 14 after taking the drug in the study groups

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 48 patients. The steps of allocating the samples to the studied groups will be done by simple randomization and by Random allocation software.

Settings and conduct
In each group, the number of patients will be 12, and on days 0, 7, and 14, imaging of the wound site of the patients will be done. Al-Zahra Hospital. 4 drug groups are prepared including 2 groups for oral use and 2 groups for local use, each group will include placebo and main drug. Both types of placebo and main drug are completely similar in appearance. Therefore, the project manager and the patient do not know the type of the main drug, which is placebo or active drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients who have undergone micrographically oriented histographic (Mohs) surgery due to skin cancer in the head and face area 2. The age of patients should be in the range of 50 to 80 years. 3. Completing the consent form to participate in the study. Patients exit criteria: 1. Unwillingness of patients to continue cooperation and follow-up 2. Surgery in an area of the body other than the head and face 3. Development of contact dermatitis following drug use 4. Failure to take medicine correctly by the patient

Intervention groups
Taking topical and oral sikaglocal medicine as a wound healer

Main outcome variables
Investigating the restorative effect of sikaglocal drug in accelerating wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220306054206N3**
Registration date: **2024-02-26, 1402/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-26, 1402/12/07**
Update count: **0**

Registration date
2024-02-26, 1402/12/07

Registrant information

Name
Parisa Mohamadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-19, 1402/11/30

Expected recruitment end date
2024-04-18, 1403/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of oral and topical Cicaglocal drug on wound healing in patients after micrographically oriented histographic surgery (Mohs surgery)

Public title
Investigating the effect of oral and topical Cicaglocal drug on wound healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have undergone Mohs surgery due to skin cancer of the head and face Age should be in the range of 50 to 80 years. Completing the consent form to participate in the study

Exclusion criteria:
Surgery in an area of the body other than the head and face Skin cancer of a type other than SCC and BCC The presence of a specific underlying disease that directly leads to a disorder in wound healing, including scleroderma and morphea

Age
From **50 years** old to **80 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize the samples, we give each drug a code and ask the patient to choose one of the codes by lottery.

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo drug is prepared by the Persian Pod company based on the drugs and provided to the presenter. 4 drug groups including 2 groups for oral use and 2 groups for local use will be prepared, each group will include placebo and main drug. The same container as the original medicine is used to make the placebo medicine, and only its contents are changed to placebo, for the oral medicine in the capsule, starch is used, and for the topical medicine, the oil base used in the preparation of the original medicine is used. Therefore, both placebo and main drugs are completely similar in appearance. Then, each drug group is named with an English letter name, which in this plan, the oral drug is named S and K and the topical drug is named H and T, and it is given to the project manager. Therefore, the project manager and the patient do not know the type of the main drug, which is placebo or active drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hazar Jarib Street, Isfahan University of Medical Sciences and Health Services, Central Center

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Isfahan

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Isfehan

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73461-81746

Approval date
2024-02-03, 1402/11/14

Ethics committee reference number
IR.ARI.MUI.REC.1402.291

Health conditions studied

1

Description of health condition studied
Ulcer

ICD-10 code
C44

ICD-10 code description
Other and unspecified malignant neoplasm of skin

Primary outcomes

1

Description
Determining the effect of oral and topical cikaglocal drug on wound healing in patients after Mohs surgery, where the wound healing score is given based on the Early Healing Index (EHI).

Timepoint
In each group, the number of patients will be 12, and on days 0, 7, and 14, imaging of the patients' wounds will be done, and the duration of drug use is 14 days.

Method of measurement
The wound healing score is based on the Early Healing Index (EHI), which evaluates wound healing using scores from 1 to 5: a wound with very poor healing receives a score of 1, while excellent healing receives a score of 5. slow

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group includes oral capsule and topical solution of Sikaglocal. The patient receives one capsule daily for 2 weeks (14 capsules) and topical solution twice a day for 2 weeks (one vial of solution). The drug is prepared by Daru Darman Parshin Pod Company, whose main composition is bromelain and, along with other items, it includes vitamin C, group B vitamins including: B2, B3, B7, vitamin D, iron, zinc, copper, Centella plant extract, and sodium. Hyaluronate is combined. The medicine is stored at room temperature. In each session, the correct way to take the medicine is explained to the patient and the method of use is indicated on the product.

Category
Treatment - Drugs

2

Description
The control group includes oral capsules and placebo topical solution. The patient receives one capsule daily for 2 weeks (14 capsules) and topical solution twice a day for 2 weeks (one vial of solution). The drug is prepared by Daru Derman Parshin Pod Company, which is an oral capsule containing starch and an oil-based topical solution. The medicine is stored at room temperature. In each session, the correct way to take the medicine is explained to the patient and the method of use is indicated on the product.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital affiliated to Isfahan University of Medical Sciences

Full name of responsible person
Parisa Mohammadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Asgari

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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Parisa Mohammadian

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is 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
All patient information can be shared because it includes age, gender, and type of disease, and the photos must be designed in such a way that it is not possible to identify people.

When the data will become available and for how long
After the article is printed, there is a place to publish the documents

To whom data/document is available
Researchers of academic and scientific centers have access to documents

Under which criteria data/document could be used
The data should not be used directly and only for sampling and comparison with their own information.

From where data/document is obtainable
Be in touch with the email of the main author of the article.

What processes are involved for a request to access data/document
After checking the applicant's email, he will have access within one month

Comments