

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Preparation and evaluation of topical glycyrrhizin-menthol-aloe vera gel and assessment its effect on the prevention of laser-induced dermatitis: a randomized controlled clinical trial

Protocol summary

Study aim

Preparation and evaluation of glycyrrhizin-menthol-aloe vera topical gel and its effectiveness in preventing laser-induced dermatitis: a randomized controlled clinical trial

Design

A randomized controlled clinical trial with double-blind parallel groups of phase 2 is on 90 patients, and the patients will be randomly divided into 3 groups of 30 people based on the RAND() function of Excel software.

Settings and conduct

This study is a randomized clinical trial that is conducted on 90 patients at Yazd Laser Therapy Center. Taking into account the criterion of entering the study, the clients will be randomly divided into 3 groups of 30 people, including those receiving glycyrrhizin-menthol-aloe vera gel, placebo (base gel) or control (without medicine). Neither the doctor nor the patient knows the contents of the medicine containers

Participants/Inclusion and exclusion criteria

Clients who have started using laser and have no history of allergies to plants such as licorice, aloe vera and mint and no skin diseases

Intervention groups

The group receiving glycyrrhizin, aloe vera, and menthol gel, which was made in the laboratory of the Faculty of Pharmacy of Yazd University of Medical Sciences under the supervision of the professors of the faculty and during the Ph.D. thesis of a pharmacy student, received topically for 15 days from the start of the laser. The control group received base gel without medication for 15 days from the start of the laser

Main outcome variables

at times 1, 2, 4, 7, 10, 15, the state of the laser site in terms of the loss of the epidermis, intensity of redness, dryness, itching (based on the table below), burning and pain (based on the visual scale VAS) and the patient's satisfaction with the use of the drug and whether the

skin in the laser area gets second degree burns or not and the need to use standard dermatitis treatment are evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N17**

Registration date: **2023-07-24, 1402/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-24, 1402/05/02**

Update count: **0**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3865

Email address

mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2024-01-10, 1402/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and evaluation of topical glycyrrhizin-menthol-aloe vera gel and assessment its effect on the prevention of laser-induced dermatitis: a randomized controlled clinical trial

Public title

Evaluation of the effect of glycyrrhizin hydrogel on laser burns

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Clients starting to use laser Clients aged 18 to 55 years
No history of licorice allergy Absence of severe systemic disease such as uncontrolled diabetes, epilepsy, immune system deficiency, etc. Willingness to participate in the study and complete the ethical consent form

Exclusion criteria:

Clients with skin disease Allergy to glycyrrhizin or any of the compounds used Exacerbation of dermatitis or 2nd degree burns Non-cooperation of the volunteer in using medicine for more than one day

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized clinical trial that is conducted on 60 patients at Yazd Laser Therapy Center. Taking into account the inclusion criteria, the participants will be randomly placed in three groups of 20 people including glycyrrhizin gel recipient, gel base, and control (without receiving any medication), and will receive the drug related to that group, based on the RAND() function of Excel software. The medicine is placed in uniform containers, and neither the doctor nor the participant knows about the contents of the tubes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, clients who have undergone laser hair removal will be included in the study after obtaining written consent. Taking into account the inclusion criteria, the clients will be placed in 3 groups of 30 people including glycyrrhizin-menthol-aloe vera gel, placebo (base gel) or control (without medicine) based

on the random numbers table. They will use the prescribed medicine twice a day under the supervision of a doctor. Neither the doctor nor the patient knows the contents of the medicine containers. After the start of the treatment at times 1, 2, 4, 7, 10, 15, the state of the laser site in terms of the loss of the epidermis, intensity of redness, dryness, itching (based on the table below), burning and pain (based on the visual scale VAS) and the patient's satisfaction with the use of the drug and whether the skin in the laser area gets second degree burns or not and the need to use standard dermatitis treatment are evaluated

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Faculty of Pharmacy, Shahid Sadoughi University of Medical Sciences

City

Yazd

Province

Yazd

Postal code

1234567890

Approval date

2023-01-11, 1401/10/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1401.184

Health conditions studied**1****Description of health condition studied**

Laser induced dermatitis

ICD-10 code

L59.8

ICD-10 code description

Other specified disorders of the skin and subcutaneous tissue related to radiation

Primary outcomes**1****Description**

Grading the intensity of skin redness

Timepoint

After starting treatment at times 1, 2, 4, 7, 10, 15

Method of measurement

The condition of the laser site in terms of the loss of the epidermis, the intensity of redness, dryness, itching, burning, and pain (based on the visual analog scale), and the patient's satisfaction with the use of the drug, and that the skin of the laser area has undergone second-degree burns. are evaluated or not, as well as the need to use the standard treatment of dermatitis.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The recipient of glycyrrhizin-menthol-aloe vera gel will use the prescribed medicine twice a day under the supervision of a doctor. In this study, clients who have undergone laser hair removal will be included in the study after obtaining written consent. Taking into account the criterion of entry into the study, the clients will be placed in 3 groups of 30 people including glycyrrhizin-menthol-aloe vera gel (prepared at the Faculty of Pharmacy of Yazd University of Medical Sciences under the supervision of the professors of the faculty and as a doctoral thesis of a pharmacy student), placebo (base gel) or control (without medicine). Twice a day and for 15 days under the supervision of a doctor, they will use the prescribed medicine topically. Neither the doctor nor the patient knows the contents of the medicine containers. After starting the treatment at times 1, 2, 4, 7, 10, 15, the condition of the laser site in terms of the loss of the epidermis, the intensity of redness, dryness, itching (based on the table below), burning and pain (based on the visual analog scale), and the patient's satisfaction with the use of the drug, and whether the skin of the laser area is subject to second-degree burns or not, and the need to use standard dermatitis treatment, are evaluated.

Category

Prevention

2**Description**

Control group: Placebo (base gel) or control (without medicine) which is filled in tubes like medicine.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Laser Center

Full name of responsible person

Fatemeh Dehghani

Street address

Yazd city, Alem Square, Shahid Sadougi Faculty of Pharmacy

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Phone

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Email

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amin Salehi

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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

Yazd 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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Dehghani

Position

Pharmacy Student

Latest degree

Medical doctor

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

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohsen Zabihi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Email

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of the data, such as the information related to the main outcome or the like, can be shared.

When the data will become available and for how long

One year after the time of publication

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data will be available only to researchers working in academic and scientific institution

From where data/document is obtainable

The data will only be available to researchers working in academic and scientific institutions through the following email address. neginasari@yahoo.com

What processes are involved for a request to access data/document

Only the data related to the main results of the study can be presented to the mentioned people after mentioning the valid reason.

Comments