

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Clinical evaluation of the effect of Glycyrrhiza glabra root hydroalcoholic extract on the second degree burn wound healing.

Protocol summary

Study aim

evaluation of the effect of Glycyrrhiza glabra root hydroalcoholic extract on the second-degree burn wound healing

Design

The clinical trial has a control group, double-blind, randomized, phase 1 on 50 patients. Excel software rand function was used for randomization

Settings and conduct

Patients are selected from patients referred to Yazd Accident and Burn Hospital based on inclusion and exclusion criteria. Patients are treated with medication under the supervision of a physician and evaluated at the end of the study. The drugs are coded in the intervention and control groups and the physician and the patient do not know its content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with second-degree burn; Patients aged 16 to 65 years; Burns should occur no more than 24 hours before the start of treatment and involve less than 15% of the body surface. exclusion criteria: Patients with skin diseases; Allergy to silver sulfadiazine or licorice; Severe systemic diseases such as uncontrolled diabetes mellitus, epilepsy, immunodeficiency and pregnant women

Intervention groups

Licorice hydrogel receiving group; Base hydrogel receiving group

Main outcome variables

Severity of erythema; Burning; Inflammation; Inflammation; edema; Wound size; Wound healing percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N5**

Registration date: **2021-05-01, 1400/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-01, 1400/02/11**

Update count: **0**

Registration date

2021-05-01, 1400/02/11

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

2021-03-02, 1399/12/12

Expected recruitment end date

2021-06-25, 1400/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effect of Glycyrrhiza glabra root hydroalcoholic extract on the second degree burn wound healing.

Public title

Clinical evaluation of the effect of Glycyrrhiza glabra root

hydroalcoholic extract on the second degree burn wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with grade 2 burns. Hip patients 16 to 65 years. The burn must have occurred 24 hours before the start of treatment and involved less than one and a half percent of the body surface.

Exclusion criteria:

Patients with skin diseases. Allergy to silver sulfadiazine or licorice. Severe systemic diseases such as uncontrolled diabetes, epilepsy, immunodeficiency and pregnant women.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with 2 degree burn who meet the inclusion criteria are placed in one of two groups A or B using random numbers obtained from the RAND function of Excel software. Licorice hydrogels or base hydrogels are each placed in a uniform container labeled A or B. So that only the first executor of the project is aware of the content of these containers and none of the doctors and patients know the content of each container.

Blinding (investigator's opinion)

Double blinded

Blinding description

Different groups of drugs are placed in uniform and coded containers, and the prescribing physician and the evaluator do not know the composition and content of each drug container.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Approval date

2019-09-01, 1398/06/10

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.179

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Burn wound healing score

Timepoint

before intervention and 3, 10 weeks after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with hydrogel containing licorice will be treated topically for 15 days and standard treatment. Patients will be instructed to use only the products mentioned in the study and the necessary warnings will be given about using other household products. Treatment of the lesion condition is evaluated for the severity of redness, burning, edema, inflammation and pain (score 0 to 4). Patients will take the prescribed medication daily. After starting treatment, patients are evaluated every 5 days for the severity of redness, burning, edema, inflammation and pain.

Category

Treatment - Drugs

2

Description

Control group: Patients with hydrogel base will be treated topically for 15 days and standard treatment. Patients will be instructed to use only the products mentioned in the study and the necessary warnings will be given about using other household products. Treatment of the lesion condition is evaluated for the severity of redness, burning, edema, inflammation and pain (score 0 to 4). Patients will take the prescribed medication daily. After starting treatment, patients are evaluated every 5 days for the severity of redness, burning, edema, inflammation and pain.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Mehrab Hospital

Full name of responsible person

Ali Bemani

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Moalem sq.

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burn.hospital@chmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masood Mirzaei

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Bahonar sq.

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mmirzaei@ssu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

School of Pharmacy

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

Yazd University of Medical Sciences

Full name of responsible person

Mohsen Zabihi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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