Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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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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