Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Formulation of a topical gel containing Lawsonia inermis extract and Aloe vera and evaluation its effects on the healing process of second degree burns: A randomized double_blinded placebo_controlled trial.

Protocol summary

Study aim

Determining the effectiveness of gel containing Henna and Aloe vera extract on the healing process of second degree burns.

Design

This study is a clinical trial with a control group, with parallel groups, double_blind, randomized, phase3, which is performed on 48 patients, using RAND function of Excel software for randomization.

Settings and conduct

It is a double_blind randomized controlled clinical trial. Patients receive a uniform product so that neither the physician nor the patient is aware of the content of the dosage form. Patients who meet the inclusion criteria will be included in the study after obtaining written consent and their information including age, gender, weight, underlying diseases, and medications will be extracted from the file. Patients receive one of the products containing Henna and Aloe vera extract or silver sulfadiazine twice a day for 10 days without dressing on the burn site. Patients are instructed to use only the products mentioned in the study and the necessary warnings about using other products. During and after treatment, on days 1, 2, 4, 7, 10, 15 and 30 the skin condition is evaluated for the severity of redness, dryness, itching, burning, and pain (score 0 to 4).

Participants/Inclusion and exclusion criteria

Patients with second degree burns aged between 18 and 65 years.

Intervention groups

Twice a day consumption of gel containing Henna extract and Aloe vera or Silver sulfadiazine.

Main outcome variables

The severity of erythema or redness, itching, burning or pain, dry skin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N21**
Registration date: **2024-09-18, 1403/06/28**
Registration timing: **prospective**

Last update: **2024-09-18, 1403/06/28**
Update count: **0**

Registration date

2024-09-18, 1403/06/28

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

2024-10-21, 1403/07/30

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Formulation of a topical gel containing Lawsonia inermis extract and Aloe vera and evaluation its effects on the healing process of second degree burns: A randomized double_blinded placebo_controlled trial.

Public title
Formulation of a topical gel containing Lawsonia inermis extract and Aloe vera and evaluation its effects on the healing process of second degree burns.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with second degree burns Patients aged 18 to 65 years

Exclusion criteria:
Patients with skin diseases Pregnant women Allergy to henna or Aloe vera

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who meet the inclusion criteria are placed in one of two treatment groups with products containing Henna and Aloe vera (group A) or Silver sulfadiazine (group B). Randomization is performed based on the RAND() function of Excel software, and based on this, a table of random numbers is prepared, and patients are placed in groups A or B, respectively, in the rows of this table, and receive the product related to their group.

Blinding (investigator's opinion)
Double blinded

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

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of the Faculty of Medicine, Shahid Sadougi University of Medical Sciences, Yazd

Street address
Alem sq.

City
Yazd

Province
Yazd

Postal code
8916978447

Approval date
2023-01-11, 1401/10/21

Ethics committee reference number
IR.SSU.MEDICINE.REC.1401.195

Health conditions studied

1

Description of health condition studied
Second degree burn

ICD-10 code
T30.0

ICD-10 code description
Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description
Severity of erythema or redness

Timepoint
During and after treetment, every two days, the skin condition is evaluated for the severity of redness, dryness, itching, burning and pain.

Method of measurement
Scoring erythema or redness using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It includes 24 patients referred to the Shohadaye Mehrab Hospital who meet the inclusion criteria, whose order and type of intervention is random based on the (RAND) function of Excel software. Patients in the intervention group use a topical gel containing Henna and Aloe vera extract prepared at the Faculty of Pharmacy of Shahid Sadoughi University of Medical Sciences in Yazd twice a day. After starting treatment,

the condition of the lesion is evaluated for redness, dryness, itching, burning and pain (score 0 to 4).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of burning of Shohadaye mehrab hospital

Full name of responsible person

Niloofar Jafarian

Street address

Shohadaye mehrab hospital center of burning Paknejad blvd. moallem aq. Yazd Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Lotfaliani

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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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Lotfaliani

Position

Assistant professor

Latest degree

Ph.D.

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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Dr. Mohsen Zabihi

Position

Associate Professor

Latest degree

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Name of organization / entity
Yazd University of Medical Sciences

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Niloofar Jafarian

Position
Student of Pharmacy

Latest degree
A Level or less

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