

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The evaluation of efficacy of topical formulation of Henna (*Lawsonia inermis*) in prevention of contact dermatitis in patients using prosthesis

Protocol summary

Study aim

The evaluation of efficacy of topical formulation of Henna (*Lawsonia inermis*) in prevention of contact dermatitis in patients using prosthesis

Design

In this study, 72 patients with lower limbs amputation who prosthesis are prescribed for them and are eligible for entering the project, and are referred to the Shiraz Red Crescent Center for Comprehensive Rehabilitation are included in the study. The patients will randomly assigned to two parallel intervention and control groups and one code is allocated to hide the group of each participant.

Settings and conduct

In this study, patients ,researcher and statistic analyzer will be blinded .

Participants/Inclusion and exclusion criteria

Inclusion criteria: lower limb amputees; prosthesis; no systemic diseases; no skin disorders. Exclusion criteria: sensitivity and allergy to henna or hair dye.

Intervention groups

Intervention group: Henna extract cream 1%, 3 times/day for 3 months Control group: placebo cream , 3 times/day for 3 months

Main outcome variables

Moisture, erythema, elasticity, itching and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171229038126N1**

Registration date: **2018-04-29, 1397/02/09**

Registration timing: **prospective**

Last update: **2018-04-29, 1397/02/09**

Update count: **0**

Registration date

2018-04-29, 1397/02/09

Registrant information

Name

Mehdi Niazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 6057

Email address

m.niazi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-20, 1397/02/30

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of efficacy of topical formulation of Henna (*Lawsonia inermis*) in prevention of contact dermatitis in patients using prosthesis

Public title

The evaluation of efficacy of topical formulation of Henna (*Lawsonia inermis*) in prevention of contact dermatitis in patients using prosthesis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Lower extremity amputation Lower extremity prosthesis
Age of 12-70 years old
Exclusion criteria:
Any diagnosed dermatological disorder Any diagnosed systemic disorder (i.e Diabetes) Pregnancy or lactation Allergy to Henna or hair coloring agents

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

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

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be divided in two equal parallel groups with block randomization method

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patients will be blinded by using similar drug tubes
The clinical investigator will not deliver the drugs
The statistician will receive the data in two groups labeled as A and B without identification

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

The road of Haft Bagh Kerman University of Medical Sciences Kerman

City

Kerman

Province

Kerman

Postal code

76169-13555

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.KMU.REC.1397.021

Health conditions studied

1

Description of health condition studied

Contact Dermatitis

ICD-10 code

L24

ICD-10 code description

Irritant contact dermatitis

Primary outcomes

1

Description

Pruritus

Timepoint

0, 1, 2, 3 months

Method of measurement

VAS (Visual Analogue Scale)

Secondary outcomes

1

Description

Skin Moisture

Timepoint

Month :0-1-2-3

Method of measurement

KC Technology

2

Description

Skin erythema

Timepoint

Month:0-1-2-3

Method of measurement

KC Technology instrument

3

Description

Skin elasticity

Timepoint

Month:0-1-2-3

Method of measurement

KC Technology instrument

4

Description

Pain

Timepoint

Month;0-1-2-3

Method of measurement

visual Analogue Scale (VAS)

5

Description

Quality of life

Timepoint

Month:0-1-2-3

Method of measurement

questionnaire

Intervention groups

1

Description

Henna extract cream 1%, 3 times/day for 3 months

Category

Prevention

2

Description

Control group: placebo cream , 3 times/day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Red Crescent ,Rehabilitation Center Shiraz

Full name of responsible person

Mehdi Niazi

Street address

Sibouyeh Boulevard, Red Crescent Rehabilitation Center Shiraz

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Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr.Mehrzaad Mehrabani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available