Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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
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Iran (Islamic Republic of)
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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 prothesis 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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