Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of topical product containing henna and turmeric with a Persian medicine based formulation with placebo in patients with contact dermatitis. Triple-blind clinical trial

Protocol summary

Study aim
Evaluation of the effectiveness of topical product containing henna and turmeric with Persian Medicine based formulation in contact dermatitis patients. Triple-blind clinical trial

Design
Triple-blind, parallel, drug-placebo randomized clinical trial in 33 adult patients with mild to moderate contact dermatitis

Settings and conduct
The study is performed on patients referred to Ahmadieh Health Center and Dermatology and Leprosy Research Center. After informing about the study and obtaining informed consent, patients are classified into intervention groups. Medicines that are given to the patients have no name but only numbers. Examinations are performed and compared before and after the intervention. The researcher, patient and data processor are unaware of the allocation of study groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults 18 and older; Acute or recurrent contact dermatitis in a person with a history of mild to moderate contact dermatitis; Declare the written consent of the patient to participate in the study and the desire to attend regular treatment and follow-up courses; Have a minimum score of one for the Redness and Itching option on the Three Item Severity Scale exclusion criteria: any type of dermatitis except contact dermatitis or heart or kidney disease or asthma or cancer; Severe contact dermatitis; Recent use of topical dermatitis medications and steroids or systemic immunosuppressants with any indication; G6PD enzyme deficiency

Intervention groups
Drug group: Cream containing turmeric, henna and Zaravand extracts Placebo group: base cream with authorized color

Main outcome variables
Severity and extent of the disease, severity of pruritus, transepidermal water loss, epidermal moisture melanin content, hemoglobin content, sebum, temperature, surface acidity of the lesion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220321054336N1**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **prospective**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date
2022-04-09, 1401/01/20

Registrant information
Name
Shabnam Khatami
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-22, 1401/03/01
Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of topical product containing henna and turmeric with a Persian medicine based formulation with placebo in patients with contact dermatitis. Triple-blind clinical trial

Public title
Evaluation of the effectiveness of topical product containing henna and turmeric with Persian medicine based formulation in patients with contact dermatitis. Triple-blind clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and above Acute or recurrent contact dermatitis in a person with a history of mild to moderate contact dermatitis (baseline Three Item Severity score in the range of 1 to 6) • Declare the written consent of the patient to participate in the study and the desire to attend regular treatment and follow-up courses • Have a minimum score of one for the redness and itching option in the Three Item Severity score
Exclusion criteria:
Other types of dermatitis except contact dermatitis Use of topical dermatitis medications (except moisturizers) in the last 2 weeks or systemic medications in the last 4 weeks Taking steroids or systemic immunosuppressants with any indication • Pregnant and lactating women • Severe contact dermatitis (Three Item Severity = 9) • Alcohol or drug addiction • Heart disease, kidney disease or asthma • Active skin disease other than contact dermatitis • History of allergies to topical medications or cosmetics (with documentation) Tattooing, scarring, and hyperpigmentation at the lesion site History of any malignant disease or active cancer G6PD enzyme deficiency
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

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

Sample size
Target sample size: **33**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we used Random Allocation software for randomization. This software is able to generate random blocks that we will use this method for randomization. Randomization is done individually using 5-unit blocks. The random sequence of samples will be performed equally as Intervention and Placebo groups using this software. For allocation concealment, sealed envelopes will be used. In this method, each of the random sequences written on a card and they are placed in the envelopes, respectively. Finally, the lid of the envelopes is glued and placed in a box, respectively. At the registration time, based on the order in which eligible participants enter the study, one of the envelopes of their choice will be opened and their assigned group will be revealed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
drug and placebo cans were coded by an expert person in the research center. Researchers, patients, data collectors, and evaluators assess the outcome, are not aware of the contents of the package and grouping, and samples were delivered at random to the patient. Patients received the number to their referral and entered the study. The number of patients was randomly selected by computer and divided into two groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of school of medicine Tehran University of Medical sciences
Street address
Room 605,sixth floor, the headquarters of Tehran University of Medical Sciences, The intersection of Keshavarz Blvd and Ghods St.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2022-03-19, 1400/12/28
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1533

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
Disease severity score on a three-item severity scale
Timepoint
Before the start of the study and2 and 4 weeks after the intervention
Method of measurement
Use a three-item intensity score(TIS)

2

Description
Itching intensity score
Timepoint
Before the start of the study and2 and 4 weeks after the intervention
Method of measurement
Use Visual Analogue Scale(VAS)

3

Description
trans epidermal water loss
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

4

Description
epidermal moisture
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

5

Description
melanin content
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

6

Description
hemoglobin content
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

7

Description
sebum content
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

8

Description
temperature
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

9

Description
surface acidity of the lesion(PH)
Timepoint
Before the start of the study and 4 weeks after the intervention
Method of measurement
Use Cutameter M P 580

Secondary outcomes

1

Description
Determining the effectiveness of the studied drug in comparison with placebo on the quality of life of patients
Timepoint
4 weeks after taking topical Persian medicine drug
Method of measurement
Use of Dermatology Life Quality Index (DLQI) questionnaire

2

Description
Determining the side effects of the studied drug
Timepoint
4 weeks after taking topical Persian medicine drug
Method of measurement
common Terminology Criteria for Adverse Events questionnaire

Intervention groups

1

Description
According to traditional sources and published articles, three components of turmeric, henna and Zaravand were selected to prepare the formulation. Extraction of each ingredient is done separately with water and ethanol solvents. The extracts are mixed in proportions of 3, 2 and 1 of turmeric, henna and Zaravand extracts and inserted with a concentration of 3-6% in a suitable base (cold cream). The ratio of components in the formulation was selected according to the traditional sources related to the Marham Ahmar formulation and with more emphasis on turmeric and reducing the possible toxicity of Zaravand. Also, the percentage of extract in the cream base was selected based on existing studies that have shown the effectiveness of turmeric and henna in skin problems such as eczema.The dose range is mentioned due to the uncertainty of the stability of the product and if the formulation is stable and the amount of Aristolochic acid is determined, a higher percentage of the extract in the formulation will be used. Patients are adults and meet the inclusion criteria. Patients are asked to use the product twice a day, one finger size (FTU = 1) at the site of skin lesions. Patients are given general advice about skincare in contact dermatitis, such as using gloves at work or using lukewarm water and mild detergents for rinsing.

Category
Treatment - Drugs

2

Description
The placebo is prepared using the base of the medicinal product (cold cream), without adding an extract, and to simulate the placebo with the drug in appearance, a few drops of permissible dye will be added. The medicine and placebo will be packed in exactly the same cans and then coded by the pharmacist

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahmadieh Persian Medicine Health Center
Full name of responsible person
Shabnam Khatami
Street address
No27, North Sarparast St, West Taleghani Ave
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2

Recruitment center
Name of recruitment center
Center for research and training in skin disease and leprosy
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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No27, North Sarparast St, West Taleghani Ave.
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shabnam Khatami

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All impersonal data of the participants without any name; Information on the main implications and all the information obtained from the research was published in the article.

When the data will become available and for how long

In the relevant article after its publication

To whom data/document is available

Everyone who has access to the published article

Under which criteria data/document could be used

After publication in the journal

From where data/document is obtainable

To the text of the published article or contact Dr. Shabnam Khatami via email at khatami.shabnam.188@gmail.com

What processes are involved for a request to access data/document

sending e mail to Dr Shabnam Khatami

Comments