

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 Ahmadiyeh 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 3656

Email address

sh-khatami@razi.tums.ac.ir

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

AgeFrom **18 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

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

Sample sizeTarget 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
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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 and 2 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 and 2 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

Ahmadih Persian Medicine Health Center

Full name of responsible person

Shabnam Khatami

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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

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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Assistant Professor

Latest degree

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Person responsible for updating data

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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