

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Formulation and physicochemical characterization of the topical preparation from *Cymbopogon citratus* (DC.) Stapf. and its effect on contact dermatitis

Protocol summary

Study aim

Formulation, standardization and physicochemical control of topical preparation from lemongrass (*Cymbopogon citratus* (DC.) Stapf) and evaluation of its effect on contact dermatitis

Design

Two arm parallel groups randomized trial with blinded postoperative care and outcome assessment online randomization using www.graphpad.com sample size : 50 people third phase of clinical trial

Settings and conduct

we will study referrals to skin and stem cells center of Tehran university of medical science. Patients will be divided into 2 groups accidentally. The first group will receive topical cream which contains herbal extract and the second group will receive placebo instead. Patients should use their medications twice a day for 8 weeks. All patients will be examined at first day of study (before using medication), 28th day and 56th day of study. Every session EASI and CTCAE questionnaires will be filled out by physician and pharmacist and pharmacist will take a picture of patients lesions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.patients who suffer from mild to moderate contact dermatitis according to EASI 2.patient older than 18 years old exclusion criteria: 1.patients who have received oral corticosteroids two months before study 2.patients who have received topical immunosuppressant one months before study 3.pregnant women 4.breastfeeding women 5.patients who have contact dermatitis history to herbal formulations 6.patients who have skin infections 7.patients who have immunosuppressive diseases

Intervention groups

This study has 2 groups: first group will receive herbal formulation and control group will receive placebo

Main outcome variables

reduction in size of contact dermatitis lesions reduction in inflammation and pruritus in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190425043372N1**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Soodeh Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 6528

Email address

s-karami@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Formulation and physicochemical characterization of the topical preparation from Cymbopogon citratus (DC.) Stapf. and its effect on contact dermatitis

Public title
Effect of Cymbopogon citratus on contact dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients older than 18 years old Patients who suffers from mild to moderate contact dermatitis according to EASI index

Exclusion criteria:
Patients who have used oral corticosteroides, 2 months before study Patients who have used topical immunosuppressants 4 weeks before study Pregnant women Breastfeeding women Patients who have contact dermatitis history to herbal formulations Patients who have skin infections Patients who have immunosuppressive diseases

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Online randomization using www.graphpad.com website, this website gives number 1 or number 2 codes to each 50 patients. Allocation concealment: Randomized Numbered drug containers: Formulations will be put in sealed little boxes with labels of 1 or 2 on them.

Blinding (investigator's opinion)
Double blinded

Blinding description
All formulations will be divided into two groups with 1 and 2 codes. number 1 belongs to the formulations which contains herbal extract and number 2 belongs to the formulations that are placebo. Patients and physician will not be informed about formulations content, just researcher (pharmacist) will be aware of formulations.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

medicine faculty, northern entrance, Poorsina street, Qods street, Enqelab street

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2019-03-04, 1397/12/13

Ethics committee reference number

IR.TUMS.VCR.REC.1397.1027

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

Eczema score according to EASI

Timepoint

Measuring EASI index at first day of study (before using topical formulation), 28 and 56 days after using formulation

Method of measurement

Eczema Area and Severity Index (EASI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: topical cream containing Cymbopogon citratus oil with paraffin base formulated in tehran university of medical science Iranian medicine

faculty ,consumption instruction: twice a day for eight weeks

Category

Treatment - Drugs

2

Description

Control group: topical cream containing paraffin formulated in Tehran university of medical science Iranian medicine faculty ,consumption instruction: twice a day for eight weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin & Stem Cell Research Center Tehran University of Medical Sciences

Full name of responsible person

Soodeh karami

Street address

No 4. Maryam Alley. South Kamranyeh Street, Skin and Stem Cell Research Center

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19379-57511

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Email

soodeh_karami@yahoo.com

Web page address

http://skinstemcell.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Roja Rahimi

Street address

No 27, North Sarparast street , West Taleqani street, Tehran

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1417653761

Phone

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Email

rojarahimi@gmail.com

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

Soodeh Karami

Position

PHD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No 180, Enqelab Blvd. , Shahid Beheshti street , Qods Town, Dr Soodeh Karami pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Medical doctor

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Medical Pharmacy

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Town,Dr Soodeh Karami pharmacy

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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