Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

To evaluate the effectiveness of topically applied chamomile–pumpkin semi-solid formulation compared with placebo in the improvement of psoriasis plaque in patients refer to dermatology clinic of Tehran University of Medical Sciences in 2016

Protocol summary

Summary

Objectives: Psoriasis is a common inflammatory skin disease with chronic and recurrent nature. First line treatment of mild cases, is topical treatment. According to available evidence in the traditional and classical medicine literature about the effect of chamomile and pumpkin in the treatment of inflammatory skin diseases, this study is designed to evaluate the effectiveness of topical formulation made from these two plants on psoriasis plaque. Design: This study is a prospective, single blinded, intrapatient comparison and phase II trial. Conduct: The patients randomly use drug and placebo on two symmetrical plaques on left and right sides of their body for one month. Participants: The population study is 43 patients attending to the dermatology clinic of Tehran University of Medical Sciences with mild to moderate psoriasis with at least two symmetrical plaques on their extensor areas. Interventions: patients use topical chamomile-pumpkin formulation and placebo on symmetrical plaques. Main outcome measures: To evaluate response to treatment, photography and estimating the amount of redness, thickness and scaling of the plaques is done before and one month after the treatment. At the end of the study, both patient and physician will determine response to treatment by specifying a number of 0 to 100 for each groups of lesions which will be analyzed in a qualitative manner. The possible side effects of the drug and placebo are recorded and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092830030N1**

Registration date: **2016-11-05, 1395/08/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-05, 1395/08/15

Registrant information

Name

Sima Kolahdooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 6697 0869

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effectiveness of topically applied

chamomile–pumpkin semi-solid formulation compared with placebo in the improvement of psoriasis plaque in patients refer to dermatology clinic of Tehran University of Medical Sciences in 2016

Public title
Effect of topical drug made from chamomile and pumpkin on psoriasis plaque improvement
Purpose
Treatment
Inclusion/Exclusion criteria
Main Inclusion criteria: Patients with mild to moderate Psoriasis (less than 10 percent of body surface area); diagnosed by a dermatologist; aged 2-60 years old of both sexes with at least two symmetrical psoriasis plaques in their extensor areas; Discontinuation of topical treatment for at least two weeks prior to the study; Lack of systemic treatment or phototherapy during 4 weeks prior to the study; Absence of skin infections or malignancy in the treatment area; Not using Medications that could Trigger Psoriasis like beta blockers; Taking a written consent form from the patient. Main Exclusion criteria: Lactation; Pregnancy; History of allergy to the active ingredient of the product; History of skin infection or skin malignancy in the treatment area; Allergic reaction to the drug or infection in treatment area; Need to start systemic therapy during the study; Occurrence of events During the study which cause anxiety, Stress or severe mental disturbance in patients; Unwillingness of patients to continue treatment.
Age
From **2 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **43**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the Tehran university of medical sciences
Street address
Sixth floor, central building of the university, St. Ghods, Keshavarz Blvd, Tehran, Iran
City
Tehran
Postal code
Approval date
2016-06-26, 1395/04/06
Ethics committee reference number
IR.TUMS.VCR.REC.1395.184

Health conditions studied

1

Description of health condition studied
psoriasis
ICD-10 code
L40
ICD-10 code description
Psoriasis

Primary outcomes

1

Description
Scaling, Thickness, Redness
Timepoint
Before treatment and one month later for each lesion
Method of measurement
Compare photos by dermatologist and assign a number from 0 to 8 (0 no symptoms, 2 mild, 4 moderate, 6 severe, 8 very severe) to each of these signs

2

Description
PSI score
Timepoint
Before treatment and one month later for each lesion
Method of measurement
The sum of redness, thickness and scaling score

Secondary outcomes

1

Description
Photography from lesions
Timepoint
Before treatment and one month later for each lesion
Method of measurement
Canon SX60 HS, with 65x zoom and 21-1365 mm eq lens and resolution 17 Megapixels

2

Description
Patient and physician overall estimation of treatment

success rate

Timepoint

Before treatment and one month later for each lesion

Method of measurement

At the end of the study, both the dermatologist and patient will determine their estimation of improvement rate in each groups of lesions by assigning a number from 0 to ± 100. These numbers will be analyzed in a qualitative manner: negative number: worsening, 0: unchanged, (0-25 %): mild improvement, [25-50%): moderate improvement), [50-75%): high improvement, [75-100%): very high improvement, 100%: full recovery.

3

Description

Evaluation of possible side effects of formulation and placebo

Timepoint

Two weeks and a month after treatment

Method of measurement

History taking and photography

Intervention groups

1

Description

Intervention group: semi-solid formulation (combination of chamomile oil and pumpkin oil in a ratio of 1 to 1) topical treatment twice daily for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Liquid paraffin with 0.1 percent chamomile essence, topical treatment twice daily for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic of Razi hospital

Full name of responsible person

Nafiseh Smaeeli

Street address

Razi Hospital, Razi dead end, Vahdat-e-Islami Square, Vahdat-e-Islami St, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Roja Rahimi

Street address

Ahmadieh traditional medicine clinic, North Sarparast Street, Palestine Square, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sima Kolahdooz

Position

Assistant of traditional medicine

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty