Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical evaluation of different topical formulations of Fumaria officinalis extract on the Vitiligo and analysis of its Fumaric acid content by HPLC.

Protocol summary

Summary

The objective of this randomized, double blind trial is to investigate the effect of topical various formulation of hydroalcoholic extract from fumaria officinalis on vitiligo. In this study 75 patients with vitiligo who meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention or control group. The patients in the intervention group will receive formulation for one symmetric section of the patches. The patients in the control group will receive none of the topical drug. In-vitro tests include: the methods of assigning the fumaric acid by HPLC, release test, viscosity and permanence test for every six formulation were done. The patients are classified into six groups, and every formulation is used for 16 weeks, then the degree of recovery was controlled in every 15 days. As regards that the patients use the formulation for one symmetric section of their bodies; it is possible to compare the patches of two symmetric sections of the body in order to find the signs of recovery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111108022N1**
Registration date: **2011-12-08, 1390/09/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-08, 1390/09/17

Registrant information

Name

Katayoun Derakhshandeh

Name of organization / entity

Hamadan University of Medical Sciences, Pharmacy school

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1590

Email address

kderakhshandeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research department of pharmacy school of Kermanshah University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of different topical formulations of Fumaria officinalis extract on the Vitiligo and analysis of its Fumaric acid content by HPLC.

Public title

Clinical evaluation of different topical formulations of Fumaria officinalis extract on the Vitiligo and analysis of its Fumaric acid content by HPLC.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: lasting more than 6 month after diagnosis, age 11-60, filling informed consent. Exclusion criterion: Pregnancy, Lactation, not filling consent form.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Kermanshah University of Medical Sciences and Health Services

Street address

Beheshti blv, Kermanshah, Iran

City

Kermanshah

Postal code

Approval date

2010-12-20, 1389/09/29

Ethics committee reference number

7/420/12188

Health conditions studied

1

Description of health condition studied

vitiligo

ICD-10 code

L80

ICD-10 code description

disorders of pigmentation

Primary outcomes

1

Description

Repigmentation rate after treatment

Timepoint

Every 2weeks during 4 months

Method of measurement

Observtion

Secondary outcomes

1

Description

Diameter reduction

Timepoint

every 2 weeks during 4 months

Method of measurement

Evaluation of diameter with precise measurement

Intervention groups

1

Description

Intervention lesion: topical formulation of hydroalcoholic extract from fumaria officinalis in three different percents for one symmetric section of the patches, three times a day, and follow up every 2 weeks for 4 months.

Category

Treatment - Drugs

2

Description

Control lesion: use the none of topical treatments on the other side of the symmetric section of patches.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Haj daie's Dermatology Clinic in Kermanshah

Full name of responsible person

Dr. Ali Ebrahimi

Street address

Golestan Street

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University Of Medical Sciences and Health Services

Full name of responsible person

Dr Farid Najafi

Street address

Kermanshah University Of Medical Sciences, Beheshti

blv, kermanshah, iran

City

Kermanshah

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, Kermanshah University Of Medical Sciences and Health Services

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr GholamReza Bahrami

Position

Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr. Ali Ebrahimi

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Soniya Mirfakhraee

Position

Pharmacy student

Other areas of specialty/work

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No.14, Golestan street, sh.shamim Alley, Kermanshah,Iran

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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