

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Formulation and Clinical Trial of a Traditional Dosage Form for Skin Depigmentation and Comparison to a Marketed Preparation in Two Groups of Patients Suffering From Vitiligo

Protocol summary

Summary

The aim of this study is to study natural dyes in traditional Persian text books and to formulate a camouflage formulation to cover skin patches of patients suffering from skin depigmentation and to perform a clinical trial on the formulation to investigate the effect of the formulation on the quality of life of the patients. To achieve that goal we are performing the clinical trial on two groups of fifteen patients. One group would be using our formulation and the other group would be using the marketed camouflage formulation. To investigate the quality of life, each group is asked to fill up DLQI questionnaire before, after and during intervention; the two formulations would be used twice daily for forty days and the questionnaire would be filled in 10 day intervals as well during the study. To investigate the possible curative effect of the two formulations an imaging technique is established and used in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205029618N1**
Registration date: **2012-08-27, 1391/06/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-27, 1391/06/06

Registrant information

Name

Ayda Hosseinkhani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1242 4255

Email address

hoseinkhan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-05, 1391/05/15

Expected recruitment end date

2012-11-05, 1391/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and Clinical Trial of a Traditional Dosage Form for Skin Depigmentation and Comparison to a Marketed Preparation in Two Groups of Patients Suffering From Vitiligo

Public title

Effect of a Traditional Dosage Form on the quality of life of the patients suffering from vitiligo and Comparison to a Marketed Preparation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: vitiligo patients from 20-60 yrs.
Exclusion criteria: under any vitiligo treatments.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Ave.
Shiraz Iran

City

Shiraz

Postal code**Approval date**

2012-02-25, 1390/12/06

Ethics committee reference number

ct-90-5958

Health conditions studied**1****Description of health condition studied**

Vitiligo

ICD-10 code

A67.2

ICD-10 code description

vitiligo, pinta

Primary outcomes**1****Description**

Quality of Life of Patients

Timepoint

before and after intervention in 10 day intervals to 40

days

Method of measurement

use of DLQI questionnaire

Secondary outcomes**1****Description**

change of skin patches color

Timepoint

before and after intervention in 10 day intervals to 40 days

Method of measurement

imaging and use of the software

Intervention groups**1****Description**

In the Intervention group the formulation under study is used twice a day as a camouflage for 40 days

Category

Treatment - Drugs

2**Description**

In the control group the marketed cosmetic product is used twice a day as a camouflage for 40 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz School of Pharmacy

Full name of responsible person

Ayda Hosseinkhani

Street address

Akbar aabad, Shiraz School of Pharmacy.

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Abdolali Mohagheghzadeh

Street address

Zand Ave, Shiraz University of Medical Sciences.

City

Shiraz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Shiraz 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

Shiraz School of Pharmacy

Full name of responsible person

Ayda Hosseinkhani

Position

Ph.D Student of Traditional Persian Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Pharmacognosy Professor, Ph.D

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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