# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 investigation the effect of the formulation on the quality of life of the patents. 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

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**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 patents 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 questionare

## 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**
Shiarz University of Medical Sciences
**Full name of responsible person**
Abdolali Mohagheghzadeh
**Street address**
Zand Ave, Shiarz 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**
Shiarz 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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*