

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of local effects of Turmeric drug in improvement of lesions in patients with vitiligo in comparison to placebo

#### Protocol summary

##### Study aim

To evaluate the effectiveness of Turmeric cream in treatment of Vitiligo lesions.

##### Design

A controlled pilot randomized double blind clinical trial

##### Settings and conduct

Thirty patients diagnosed with Vitiligo by the consultant dermatologist who will be referred to the Skin and Stem Cell Research Center of Tehran University of Medical Sciences will be considered to be included in our investigation. The quality of life index and photos from lesions will be used for the assessment of our patients. These parameters will be collected at baseline and monthly intervals for up to four months. The total duration of this research will be four month. The patients, researcher, observer dermatologist, and analyses will be blinded thorough out this investigation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with stable disease for at least 3 months ; Less than 20% of body involvement and symmetrical lesions. Non-inclusion criteria: Generalized and progressive vitiligo ; pregnancy or lactation ; allergy to Curcumin ; resistant to other vitiligo therapies and malignant or active skin infections.

##### Intervention groups

Intervention group 1: effectiveness of turmeric cream in improvement of vitiligo lesions ; this cream will be used twice daily for 4 months. Intervention group 2: effectiveness of placebo in improvement of vitiligo lesions ; this cream will be used twice daily for 4 months.

##### Main outcome variables

size of lesions , noticeability of lesions and percentage of re-pigmentation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180910040994N1**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **retrospective**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

##### Registration date

2019-08-05, 1398/05/14

##### Registrant information

###### Name

Samin Jalalmanesh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2228 4858

###### Email address

s.j1994@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

2018-10-20, 1397/07/28

##### Actual recruitment end date

2019-05-14, 1398/02/24

##### Trial completion date

2019-09-21, 1398/06/30

##### Scientific title

Evaluation of local effects of Turmeric drug in improvement of lesions in patients with vitiligo in comparison to placebo

##### Public title

Effect of Turmeric in treatment of Vitiligo

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Suffering from vitiligo Stability of lesions for at least 3 months Less than 20 percent of skin involvement Having symmetrical lesions

**Exclusion criteria:**

Generalized or progressive vitiligo pregnancy or lactation any history of allergy to Curcumin patients who are resistant to other vitiligo therapies such as immunomodulators drugs , photo-therapy and etc. any malignancy or active skin infections

**Age**

From **8 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Lesions with equal size and intensity on the left and right side were chosen for the trial.

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Lesions with equal size and intensity on the left and right side were chosen for the trial.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, simple randomization method is used in left and right subgroups in which one side is always for drug and the other side is always for placebo. A package is given to patients containing 2 creams, including turmeric cream and placebo. The placebo is devoid of the active ingredient of Curcumin and is otherwise similar to the drug. These two creams is labeled with right and left by a third person that the information about them is only available to that person and the investigator, patient and observer dermatologist are not aware of the content of the creams. The patient should apply the creams twice a day at the specified side for four months.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patient , researcher and the observer dermatologist of the study are all blinded to the randomization state in the investigation. In addition , evaluation of the efficacy of the drug will be scored by 2 blinded dermatologists by comparing before and after treatment photos at the end

of the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

pilot study

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran branch, Islamic Azad University of Medical Sciences

**Street address**

Tehran branch, Islamic Azad University of Medical Sciences, Khaghani Street, Shariati Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1916893813

**Approval date**

2019-03-11, 1397/12/20

**Ethics committee reference number**

IR.IAU.TMU.REC.1397.328

**Health conditions studied**

**1**

**Description of health condition studied**

vitiligo

**ICD-10 code**

L80

**ICD-10 code description**

Vitiligo

**Primary outcomes**

**1**

**Description**

size of lesions

**Timepoint**

at baseline and 1,2,3 and 4 months after using the drug

**Method of measurement**

imagej application

**2**

**Description**

notice ability of lesions

**Timepoint**

at the end of the study

## Method of measurement

Vitiligo Noticeability Scale Questionnaire

### 3

#### Description

percentage of re-pigmentation

#### Timepoint

at baseline and 1,2,3 and 4 months after using the drug

#### Method of measurement

taking photo under wood lamp

## Secondary outcomes

### 1

#### Description

Quality of life score in patients with vitiligo

#### Timepoint

before initiation of treatment and after finishing it

#### Method of measurement

Vitiligo Quality of Life Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Turmeric cream 5% produced by Seagull Laboratory will be used on the lesions, twice a day, for 4 months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Moisturizing cream containing yellow color with cosmetic grade will be used on the lesions, twice a day, for 4 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Skin and Stem Cell Research Center, Tehran  
University of Medical Sciences

##### Full name of responsible person

Dr.Parvin Mansouri

##### Street address

Ground floor, No.4 , Maryam closed alley, Not reaching the crossroad of Kamraniyeh, Pasha Zahri Street. (South Kamraniyeh) , Sadr Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1978812345

#### Phone

+98 21 2221 2537

#### Email

mehdirj@aol.co.uk

#### Web page address

http://skinstemcell.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr. Farshad Hashemian

##### Street address

Islamic Azad University Of Pharmaceutical Sciences ,  
Yakhchal St. , Shariati St. , Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1941933111

##### Phone

+98 21 2264 0054

##### Email

fhashemian@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### 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

Islamic Azad University

##### Full name of responsible person

Mehdi Rajabi

##### Position

assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

**Street address**

Islamic Azad University Of Pharmaceutical Sciences ,  
Yakhchal St. , Shariati St. , Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1941933111

**Phone**

+98 21 2264 0051

**Fax****Email**

mehdirj@aol.co.uk

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parvin Mansouri

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Second floor , Shooan building , Sheybani Alley ,  
North Kamraniyeh

**City**

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**Province**

Tehran

**Postal code**

1978854321

**Phone**

+98 21 2615 1500

**Email**

mansorip@sina.tums.ac.ir

**Web page address**

<http://parvinmansouri.com>

**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Samin Jalalmanesh

**Position**

Pharm.D Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Islamic Azad University Of Pharmaceutical Sciences ,  
Yakhchal St. , Shariati St. , Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1941933111

**Phone**

+98 21 2264 0051

**Fax****Email**

s.j1994@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The trial results , satisfaction of treatment forms and vitiligo quality of life questionnaire and informed consent form will be supplied.

**When the data will become available and for how long**

on completion of our investigation.

**To whom data/document is available**

That will be only decided by the Author and correspondent author.

**Under which criteria data/document could be used**

only for approval of our research and medical purpose (patients agreements and confirmation is essential)

**From where data/document is obtainable**

Correspondent author

**What processes are involved for a request to access data/document**

an official letter to request which indicates the reasons of request.

**Comments**