Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Turmeic 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 Siences
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 Kamraniyrh) , 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
Tehran
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