

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Therapeutic effects of topical fluorouracil on vitiligo lesions

Protocol summary

Study aim

Evaluation of therapeutic effect of 5 Fluorouracil on vitiligo lesions

Design

The study will be performed on 25 patients who have inclusion criteria. 3 lesions will be selected in each patients. Patients selection is non-randomized, however the lesions in each patient will be chosen according to simple randomized method of closed envelop.

Settings and conduct

The study will be held in dermatology clinic of Emam Reza Hospital, Mashhad, Iran. As patients are aware to the therapeutic procedures, patients and the researcher are not blind to the allocation. Pigmentation assessors as well as analyzer are blind to the group allocations. In each patient, 3 lesions will be selected. Microneedling with Dermapen will be done on two depigmented lesions. The first lesion will also undergo close dressing of 5 fluorouracil for 30 minutes. The third lesion will remain with no treatment. The procedure will be done each 2 weeks for 3 months. After each session a photograph will be taken from the lesions. Re-pigmentation will be scored by two blinded dermatologist as follows: 0-25% pigmentation:1; 25-50% pigmentation:2; 50-75% pigmentation :3; 75-100% pigmentation: 4.

Participants/Inclusion and exclusion criteria

Entrance criteria: patients over 10 years of age ; refractory lesions to 3 months NB-UVB therapy; Lesions should be distal to elbow/knee (except palms and soles)
Non-entry criteria: active koebner phenomenon ; active infection at the lesion site ; serious systemic illness

Intervention groups

First lesion undergoes microneedling plus 5FU dressing for 30 minutes. Second lesion undergoes only microneedling. The third lesion leave without treatment.

Main outcome variables

Re-pigmentation percent; Re-pigmentation start time; Re-pigmentation pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180602039939N1**

Registration date: **2021-02-24, 1399/12/06**

Registration timing: **prospective**

Last update: **2021-02-24, 1399/12/06**

Update count: **0**

Registration date

2021-02-24, 1399/12/06

Registrant information

Name

Sadegh Vahabi-Amlashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3845

Email address

vahabis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of topical fluorouracil on vitiligo

lesions

Public title
Effect of topical fluorouracil on vitiligo

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age above 10 years Refractory lesions after 3 month of NB-UVB therapy Lesions distal to elbow/knee (except palms and soles) Signed written informed consent
Exclusion criteria:
 Active cobner phenomenon at the lesion site Active infection at the lesion site Lesions more than 10 cm Pregnancy/breastfeeding Bleeding diseases Immunosuppress patients

Age
From **10 years** old

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **25**
 More than 1 sample in each individual
 Number of samples in each individual: **3**
 3 vitiligo lesions in each individual. One underwent microneedling plus %FU; one underwent only microneedling; one with no treatment

Randomization (investigator's opinion)
Randomized

Randomization description
 Randomization is based on a table of random numbers. First ,we prepare a random list as follows:. 3lesions will be choosen in every patients, for the three modalities, we will have following conditions: 1) Lesion 1treatment N, lesion 2 treatment NF, lesion 3control. 2) Lesion 1 treatment NF, lesion 2 treatment N, lesion 3 control 3) Lesion 1control, lesion 2 treatment N, lesion 3treatment NF 4) Lesion 1control, lesion 2treatment NF, lesion 3treatment N 5) Lesion 1treatment N, lesion 2control, lesion 3 treatment NF 6) Lesion 1treatment NF, lesion 2control, lesion 3 treatment N Each of these arrangements is placed in a sealed envelope. Then, based on the table of random numbers, the envelopes are given to patients. We begin from a point in table of random numbers and write the numbers and ignore numbers greater than 6 , continue to reach the desired sample size . Give every patient the determined envelope. For example consider the numbers from the table: 5179483 First patient envelope 5 , secound patient envelope 1, ignore the 7and 9 , third patient envelope 4 and

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessors who score the pigmentation after therapeutic procedure as well as the analyzer will be

blind to the allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee, Mashhad University of Medical Sciences, Mashhad, Iran
Street address
 Dermatology ward, Emam Reza Hospital, Emam Reza Square, Mashhad, Iran
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9177744685

Approval date
2019-12-15, 1398/09/24

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.666

Health conditions studied

1

Description of health condition studied
vitiligo

ICD-10 code
L80

ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Re-pigmentation ratio;

Timepoint
Each 2 weeks until 3 months

Method of measurement
Scoring according to the dermatologist diagnosis

Secondary outcomes

1

Description
Re-pigmentation start time

Timepoint

Each 2 weeks until 3 months

Method of measurement

Scoring according to dermatologist diagnosis

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

Intervention group: first intervention group: A vitiligo lesion on patient's limbs. Microneedling with 1 mm depth following 30 minutes of 5 Fluorouracil closed bandage on the lesion

Category

Treatment - Drugs

2**Description**

Intervention group: second intervention group: only microneedling with 1 mm depth

Category

Treatment - Other

3**Description**

Control group: vitiligo lesion will remain without any treatment

Category

Other

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

Dermatology Clinic, Emam Rea Hospital, Mashhad, Iran

Full name of responsible person

Dr Sadegh Vahabi

Street address

Emam Reza Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177744685

Phone

+98 51 3858 3845

Email

vahabis@mums.ac.ir

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Mashhad University of Medical Sciences, Mashhad, Iran

Street address

Vice Chancellor for Research, Daneshgah Avenue, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Sadegh Vahabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No 98; Dehkoda 3, Rezashahr, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177744685

Phone

+98 51 3878 6692

Email

vahabis@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sadegh Vahabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No 98, Dehkhoda 3, Rezashahr, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177744685

Phone

+98 51 3878 6692

Email

vahabis@mums.ac.ir

Razavi Khorasan

Postal code

9177744685

Phone

+98 51 3878 6692

Email

vahabis@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further data are available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Written informed consent as well as analytical file and final study report could be shared by the authors.

When the data will become available and for how long

Data will become available 3 months after the study

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

No change should be performed on available data

From where data/document is obtainable

Applicant should make communication by IRCT secretariat or personal E-mail

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

Applicant should make communication by IRCT secretariat or personal E-mail

Comments

-

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sadegh Vahabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

No 98, Dehkhoda 3, Rezashahr, Mashhad, Iran

City

Mashhad

Province