

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of efficacy of microdermabrasion in association with Tacrolimus ointment plus Elocome ointment in compare with pimecrolimus ointment plus Elocome oint in patients with vitiligo

Protocol summary

Summary

In this survey we will assay the effect of microdermabrasion in combination with Tacrolimus ointment and Elacomin ointment in treatment of vitiligo. It has been designed as a single-blind randomized clinical trial. 47 patients with vitiligo will be included in the study through the inclusion criteria of men and women aged 18 to 70 years; able to read, understand and sign patient informed consent; presenting with at least two patches symmetrically on both sides of the body, with the lesions being stable for more than 6 months prior to the study. The use of all topical medications should be discontinued for two weeks before recruiting the patients to the study. Subjects should also discontinue their phototherapy from one month previous to the study. An 8-weeks treatment of Picrolimous (twice a day) & Elacom (1week, daily /1week withdrawal) will be taken to the patients, and Microdermabrasion is prescribed every 2 weeks with single direction patches from the normal skin of the periphery to the depigmented center of the lesion. The patients with abnormal liver function tests & thyroid test; any evidence of local infection at the site of intervention, any evidence of spontaneous re-pigmentation; pregnancy and lactation; and subjects who state no satisfaction to participate at any stage of the study will be excluded. The outcomes of the survey will be considered as the recovery rates after two months of treatment; according to the assessment of two dermatologists based on the digital photos will be taken at each sessions (score 0-4).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212059800N3**
Registration date: **2013-08-06, 1392/05/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-06, 1392/05/15

Registrant information

Name

Parvin Mansouri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6659 5911

Email address

mansorip@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Skin stem cell research center-Tehran university of medical sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of microdermabrasion in association with Tacrolimus ointment plus Elocome

ointment in compare with pimecrolimus ointment plus Elocome oint in patients with vitiligo

2012-09-30, 1391/07/09

Ethics committee reference number
91-03-150-19555-77316

Public title

Evaluation of efficacy of microdermabrasion in association with Tacrolimus oint plus Elocome oint in compare with pimecrolimus oint plus Elocome oint in patients with vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age range 18 to 70 years; existence of 2 vitiligo symmetrical patch in both side of body; not taking local drugs from 2 weeks before the study; no photo therapy from one month before the study; stable for 6 months prior to study. Exclusion criteria: evidence of local infection at the site of testing; evidence of spontaneous re-pigmentation; abnormal liver function tests & thyroid tests; pregnant and lactating mothers; no satisfaction to participate at any stage of the study.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science and Health Service

Street address

Central administration of university, Ghodss St., Keshavarz Blvd

City

Tehran

Postal code

1417653761

Approval date

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

One of the common pigmentation disorders , Depigmented pathes in diffrent size

Primary outcomes

1

Description

Patient Clinical Healing

Timepoint

In the weeks 0, 2, 4, 6 & 8

Method of measurement

According to two dermatologist assessment based on digital photos of therapeutic sessions (score 0-4).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Microdermabrasion combined with two topical cream (Tacrolimus + Elocome)

Category

Treatment - Devices

2

Description

Intervention2: combination of two topical creams (Tacrolimus + Elocome)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin clinic of Imam Khomeini hospital

Full name of responsible person

Dr. Parvin Mansouri

Street address

Imam Khomeini hospital, Keshavarz BLV.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Parvin Mansouri

Street address

Skin Ward, Imam Khomeini Hospital, Khashavarz Blv.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Science

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

Shahid Beheshti University of Medical Science

Full name of responsible person

Dr.Somaih Hejazi

Position

Dermatology Resident

Other areas of specialty/work

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Position

Professor of Dermatology

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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