Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of topical 1% phenytoin combined with fractional CO_2 laser versus topical 5-fluorouracil combined with fractional CO_2 laser in the treatment of non-segmental vitiligo

Protocol summary

Study aim

To compare the efficacy and safety of fractional CO_2 laser combined with topical phenytoin 1% versus fractional CO_2 laser combined with topical 5-fluorouracil (5-FU) in the treatment of non-segmental vitiligo

Design

Randomized, single-blind, split-body clinical trial with an intra-participant comparison. Each participant contributes two comparable vitiligo lesions, which are randomly allocated to fractional CO_2 laser plus topical phenytoin 1% or fractional CO_2 laser plus topical 5-fluorouracil (5-FU). Target sample size: 26 participants. Two lesions are assessed per participant

Settings and conduct

This single-blind, split-body trial will be conducted at Razi Hospital. Participants receive both interventions on two comparable vitiligo lesions, with treatment allocation randomized per lesion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: clinical diagnosis of non-segmental vitiligo; willingness to participate and provide written informed consent; presence of at least two suitable, comparable vitiligo lesions; and no contraindication to the laser or study medications. Exclusion criteria: pregnancy or breastfeeding; known hypersensitivity to phenytoin or 5-fluorouracil; inability or unwillingness to comply with the study procedures or follow-up; previous phototherapy for vitiligo; history of systemic treatment for vitiligo; and vitiligo lesions limited to the face.

Intervention groups

Group 1: Fractional CO_2 laser followed by topical phenytoin 1% applied to the assigned lesion. Group 2: Fractional CO_2 laser followed by topical 5-fluorouracil (5-FU) applied to the assigned lesion. Both treatments are compared within each participant using two comparable lesions.

Main outcome variables

Change in VASI score. Percentage of lesion repigmentation. Comparison of treatment response between the phenytoin and 5-FU groups. Incidence of local adverse effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261113071770N1**
Registration date: **2026-11-19, 1405/08/28**
Registration timing: **prospective**

Last update: **2026-11-19, 1405/08/28**
Update count: **0**

Registration date

2026-11-19, 1405/08/28

Registrant information

Name

Nima Fathi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2028-01-21, 1406/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical 1% phenytoin combined with fractional CO_2 laser versus topical 5-fluorouracil combined with fractional CO_2 laser in the treatment of non-segmental vitiligo

Public title

Evaluation of the effect of topical 1% phenytoin combined with fractional CO_2 laser versus topical 5-fluorouracil combined with fractional CO_2 laser in the treatment of non-segmental vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of non-segmental vitiligo Willingness to participate and signing the informed consent form. Presence of at least two symmetric and similar lesions for comparison. No contraindications for fractional

Exclusion criteria:

Pregnancy or lactation. History of hypersensitivity/allergy to Phenytoin or 5-Fluorouracil. Lack of patient cooperation or withdrawal from the study. History of phototherapy prior to study entry. History of receiving systemic treatments for vitiligo. Patients whose lesions are limited only to the face.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **26**

More than 1 sample in each individual

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

Each patient contributes two symmetrical vitiligo lesions. Each lesion is randomly assigned to one of the two intervention groups (Laser + Phenytoin 1% cream or Laser + 5-Fluorouracil cream) to facilitate an intra-patient (split-body) comparison

Randomization (investigator's opinion)

Randomized

Randomization description

The study utilizes a randomized, split-body design. Each patient serves as their own control. Randomization is performed using a block randomization method (block size of 4) generated via computer software (e.g., Random Allocation Software). The allocation sequence is concealed using sequentially numbered, opaque, sealed envelopes. For each patient, two symmetrical vitiligo lesions are identified and randomly assigned to receive either fractional CO_2 laser + topical Phenytoin 1% or fractional CO_2 laser + topical 5-Fluorouracil (5-FU).

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is conducted as a single-blind trial. Topical Phenytoin 1% cream and 5-Fluorouracil (5-FU) cream are prepared in identical, pre-coded containers with similar appearance and consistency. The participants (patients) are completely unaware of which specific treatment is applied to each lesion. The care providers, investigators, and outcome assessors are aware of the treatment allocation for clinical and evaluative purposes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Approval date

empty

Ethics committee reference number

2

Ethics committee

Approval date

empty

Ethics committee reference number

3

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Razi Hospital, Vahdat-e Eslami St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

0000000000

Approval date

2026-11-11, 1405/08/20

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1405.487

Health conditions studied

1

Description of health condition studied

ICD-10 code
ICD-10 code description

2

Description of health condition studied
Non-segmental vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Change in Vitiligo Area Scoring Index (VASI) score
Timepoint
Baseline (before intervention) and at the end of months 1, 2, 3, and 4 after the start of intervention
Method of measurement
Clinical evaluation using the Vitiligo Area Scoring Index (VASI) scale calculated based on hand units and percentage of depigmentation

Secondary outcomes

empty

Intervention groups

1

Description
Category
empty

2

Description
Category
empty

3

Description
Intervention group: Intervention group 1: Fractional CO_2 laser combined with topical phenytoin 1% applied to the assigned vitiligo lesion.
Category
Treatment - Drugs

4

Description
Intervention group2: Active control group: Fractional CO_2 laser combined with topical 5-fluorouracil (5-FU) applied to the assigned vitiligo lesion.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

2

Recruitment center

3

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr.safora shakoei nezhad
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Vahdat-e Eslami St., Tehran
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1199663911
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Email
razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
nimafathi
Street address
tehran.iran.vahdat eslami street.razi hospital
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nimafathee29677@gmail.com
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 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
Tehran University of Medical Sciences
Full name of responsible person
dr safora shakoei nezhad
Position
professor of dermatology
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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
Undecided - It is not yet known if there will be 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