Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness Of Fractional Carbon dioxide LASER with Topical Methotrexate Vs Topical PUVASOL in Treatment of Vitiligo-RCT

Protocol summary

Study aim

The aim to the study is to compare the effectiveness of fractionated resurfacing carbon dioxide LASER and topical methotrexate with topical PUVASOL in cases of vitiligo effecting less than 10% body surface area.

Design

Two arm parallel group randomized control trial with blinded outcome assessment by a neutral assessor

Settings and conduct

The trial will be conducted in dermatology outpatient department of a tertiary care hospital.30 patients will be selected based on inclusion/exclusion criteria. They will be randomized into 2 groups of 15 by allocation concealed randomization in the form of selecting one of the 2 sealed envelopes. Patients and assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients willing to participate in the study; of age group of 10 -70 years; Vitiligo involving less than or equal to 10% body surface area. Exclusion Criteria: Patients using or have used other treatments for vitiligo; Pregnant women or lactating women; segmental vitiligo; Patients on immunosuppressant medications; Patients having contraindication to methotrexate or PUVASOL.

Intervention groups

For Group A, a 10,600-nm fractional carbon dioxide laser device will be used with a resurfacing mode followed by topical methotrexate application. 3 sessions will be done at 2weeks a part interval. Group B will be advised topical psoralen i.e. Methoxsalen .5% ointment is to be applied for 45 minutes on the vitiligous patch prior to sunlight exposure followed by photo exposure for 5 to 10 minutes. Patients will be examined monthly for 2 months.

Main outcome variables

Clinical improvement: 1, < 25% minimal re-pigmentation; 2, 26–50% mild re-pigmentation; 3, 51–75% moderate re-pigmentation; 4, >75% excellent re-pigmentation. Patient satisfaction. 1. Unsatisfied, 2. Partially satisfied, 3. Completely satisfied.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230816059168N2**
Registration date: **2024-03-03, 1402/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-03, 1402/12/13**
Update count: **0**

Registration date

2024-03-03, 1402/12/13

Registrant information

Name
Sakina Sadiq Malik
Name of organization / entity
National University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-01, 1402/12/11

Expected recruitment end date

2024-07-01, 1403/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness Of Fractional Carbon dioxide LASER with Topical Methotrexate Vs Topical PUVASOL in Treatment of Vitiligo-RCT

Public title

Fractional Carbon dioxide LASER with Topical Methotrexate Vs Topical PUVASOL in Treatment of Vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients willing to participate in the study Patients of age group 10 -70 years. Vitiligo involving less than or equal to 10% body surface area.

Exclusion criteria:

Patients using or have used other treatments for vitiligo in the recent past Pregnant women or lactating women Patients with segmental vitiligo Patients on immunosuppressant medications due to other diseases Patients having connective tissue diseases, epilepsy or photosensitivity disorders Patient having previous radiotherapy or phototherapy. Patients with personal or family history of melanoma and non-melanoma skin cancers Patients having contraindications to methotrexate or PUVASOL therapy

Age

From **10 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be used to divide the study sample into two groups .Unit of randomization will be individual with the help of giving random sealed envelope to the patients. Allocation concealment will be carried out.

Blinding (investigator's opinion)

Double blinded

Blinding description

Besides principal investigator and her assistant, no one in the study i.e. Patients or the neutral assessor will know about the treatment modality used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commitee Pak Emirates Hospital Rawalpindi

Street address

Saddar,Rawalpindi

City

Rawalpindi

Postal code

44000

Approval date

2024-02-21, 1402/12/02

Ethics committee reference number

A/28/ERC/O3/2024

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

clinical improvement

Timepoint

At the end of 1st and 2nd month

Method of measurement

A blinded independent medical observer will perform clinical assessments using the following grading scale for all 30 patients: 1, < 25% minimal re-pigmentation; 2, 26–50% mild re-pigmentation; 3, 51–75% moderate re-pigmentation; 4, >75% excellent re-pigmentation.

2

Description

Patient satisfaction

Timepoint

At the end of 1st and 2nd month

Method of measurement

Patient satisfaction will also be assessed by grading scale i.e. 1. Unsatisfied, 2. Partially satisfied, 3. Completely satisfied.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Fractional Carbon dioxide laser followed by topical methotrexate. Topical eutectic mixture of local anesthetic cream will be applied over the patient's lesions for 30- 45 min. A 10,600-nm fractional carbon dioxide (CO_2) laser device will be used. Key laser parameters included will be; a resurfacing mode, pulse energy of 70–100 J/cm2, coverage and a spot density of 150 spots/cm2 (static mode). After each session topical 25mg/ml methotrexate injection, not more than 0.3 ml will be massaged on the treated area and allowed to air dry. Patient will be given methotrexate to apply as few drops on the affected area once daily for 3 days after procedure. 4 sessions were done at 2weeks a part. Patients will be examined monthly for 2 months for assessment of re-pigmentation.

Category
Treatment - Other

2

Description
Intervention group 2: Topical PUVASOL. People in this Group will be advised topical psoralen with the name of Lukodermine by Howards Pharma. The ointment contains Methoxsalen as its active ingredient and comes in a pack size of 30gm .5% ointment is to be applied for 45 minutes on the vitiligous patch prior to sunlight exposure. Initially photo exposure will be done for 3 minutes and then incrementally increased by 30 seconds every time until a moderate persistent erythema or maximal exposure time of 10 minutes will be achieved. This treatment will be done thrice a week. Treated area will be washed with soap and water and sunscreen will be applied with the spf of 60 or more. Patients will be examined monthly for 2 months for assessment of re-pigmentation.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology OPD of Pak Emirates Hospital Rawalpindi

Full name of responsible person
Dr. Sakina Sadiq Malik

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Self

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
NUMS-Pakistan

Full name of responsible person
Sakina Sadiq Malik

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this 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
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
EFFECTIVENESS OF FRACTIONAL CARBONDIOXIDE LASER WITH TOPICAL METHOTREXATE VS TOPICAL PUVASOL IN TREATEMENT OF VITILIGO-RCT
When the data will become available and for how long
After publication and will be available through research gate indefinitely
To whom data/document is available
It will be open access.
Under which criteria data/document could be used
Will depend on publishing jiurnal policy
From where data/document is obtainable
Research gate, Journals website
What processes are involved for a request to access data/document
Sharing of complete article request
Comments