Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effectiveness of co2 fractional laser with Platelet-Rich Plasma (PRP) and excimer lamp in comparison with co2 fractional laser with local tacrolimus and excimer lamp in patients with vitiligo

Protocol summary

Study aim

Determining the effectiveness of fractional co2 laser with Platelet-Rich Plasma (PRP) and excimer lamp in comparison with fractional co2 laser with local tacrolimus and excimer lamp in patients with vitiligo referred to Afzalipour Hospital in Kerman

Design

Clinical trial, with parallel, double-blind, randomized, single-phase groups on 36 patients. A table of numbers was used for randomization.

Settings and conduct

Patients in both groups receive three sessions of CO2 fractional laser at one-month intervals and an excimer lamp twice a week for a maximum of 12 weeks. In addition to laser injection, patients in group A use PRP injection and patients in group B use 0.1% tacrolimus ointment. Burning, itching, dryness, redness, flushing, scaling telangiectasia, secondary infection, and type of repigmentation are assessed by a physician who does not know the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age with vitiligo who have not received any treatment for vitiligo for 3 months prior to enrollment Exclusion criteria: Uncontrolled systemic diseases, renal failure, history of allergy to calcineurin inhibitors and macrolides, Unstable vitiligo, age under 18, segmental vitiligo, involvement of more than 20% of the skin surface, history of autoimmune disease and use Other treatments, patient with Koebner-positive history, history of colloid and pregnancy and lactation

Intervention groups

For group A patients, in addition to excimer laser and CO2, PRP injection is performed monthly. Group B patients are treated with 0.1% tacrolimus ointment on the skin twice a day from the next day.

Main outcome variables

Burning, itching, dryness, redness, flushing, scaling telangiectasia, secondary infection and type of repigmentation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210125050139N1**
Registration date: **2021-07-18, 1400/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-18, 1400/04/27**
Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Saleh Solhjou

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 77 3424 0219

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of co2 fractional laser with Platelet-Rich Plasma (PRP) and excimer lamp in comparison with co2 fractional laser with local tacrolimus and excimer lamp in patients with vitiligo

Public title
Efficacy of fractional co2 laser with PRP in patients with vitiligo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from vitiligo Age over 18 years They have not received any treatment for vitiligo for 3 months before enrollment Among the patients referred to Afzalipour Hospital, Besat Clinic and Dermatology Center The diagnosis is made clinically by a dermatologist Confirmation of the disease by means of examination with a Wood lamp
Exclusion criteria:
Uncontrolled systemic diseases renal failure history of allergy to calcineurin inhibitors and macrolides age under 18 segmental vitiligo involvement of more than 20% of the skin surface history of autoimmune disease and use of other treatments patient With a positive Coubern history history of colloid and pregnancy and lactation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **18**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization was done using minitab 16 software (Mini Tab Inc.)
Blinding (investigator's opinion)
Triple blinded
Blinding description
this is a triple-blind study for outcome assessor , patients and analyzor.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Ebne Sina Ave., Tahmasb Abad Blvd.
City
Kerman
Province
Kerman
Postal code
761614111
Approval date
2021-02-13, 1399/11/25
Ethics committee reference number
IR.KMU.AH.REC.1399.165

Health conditions studied

1

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

Primary outcomes

1

Description
Lesion area
Timepoint
at base line and 1, 2, 3, 4, 5 and 6 months later
Method of measurement
Measure the diameters of the depigmented lesion using a ruler

2

Description
disease activity
Timepoint
at base line and 1, 2, 3, 4, 5 and 6 months later
Method of measurement
Measurement of disease activity based on VIDA SCORE

3

Description
percentage of improvement
Timepoint

at base line and 1, 2, 3, 4, 5 and 6 months later

Method of measurement

By clinical examination of the lesion and measuring the percentage of lesion healing compared to the primary lesion

Secondary outcomes

1

Description

Erythema

Timepoint

at base line and 1, 2, 3, 4, 5 and 6 months later

Method of measurement

by physical examination and classification of the severity of adverse effects to mild , moderate and severe

2

Description

scaling

Timepoint

at base line and 1, 2, 3, 4, 5 and 6 months later

Method of measurement

by physical examination and classification of the severity of adverse effects to mild , moderate and severe

3

Description

pruritis

Timepoint

at base line and 1, 2, 3, 4, 5 and 6 months later

Method of measurement

by physical examination and classification of the severity of adverse effects to mild , moderate and severe

4

Description

secondary

Timepoint

at base line and 1, 2, 3, 4, 5 and 6 months later

Method of measurement

With clinical examination of the lesions and the presence of signs of infection such as purulent discharge and hotness

Intervention groups

1

Description

Intervention group: Co2 fractional laser (; Italy; Energy, 100mj; density, 100 / cm2; 2 passes DEKA) with, dwell time: 400, power: 6 w, dot mode spacing: 550. 3 sessions with one month intervals and lamp excimer (Medflash II, Italy; 308nm) twice a week for a maximum of 12 weeks starting at 0.5 J / cm2. In this group, in addition after the PRP preparation, we inject 0.1 cc of the solution into the patient's blood at a distance of 1 cm.

Category

Treatment - Devices

2

Description

Control group: Co2 fractional laser (; Italy; Energy, 100mj; density, 100 / cm2; 2 passes DEKA) with, dwell time: 400, power: 6 w, dot mode spacing: 550 Three sessions with one month intervals and lamp excimer (Medflash II, Italy; 308nm) twice a week for a maximum of 12 weeks starting at 0.5 J / cm2. In this group, in addition to this topical cream Tacrolimus 0.1% of Tehran Shimi Pharmaceutical Company is used twice a day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Maryam Khalili

Street address

Imam high way, Afzalipour Hospital

City

Kerman

Province

Kerman

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7616913911

Phone

+98 34 3132 8328

Email

maryam_khalili36@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Ebne sina Aveue, Jahad Blvd

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7619813159

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abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Maryam Khalili

Position
Assistant professor of dermatology

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Maryam Khalili

Position
Assistant professor of dermatology

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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