

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Autologous melanocyte - keratinocyte suspension transplantation in patients with postburn leukoderma Comparison of two techniques to prepare the recipient site: Dermabrasion Versus Erbium: YAG laser

Protocol summary

Summary

Objectives: Autologous melanocyte - keratinocyte suspension transplantation in patients with postburn leukoderma Comparison of two techniques to prepare the recipient site: Dermabrasion Versus Erbium: YAG laser. Design: Randomized, Not blinded, Clinical trial. Setting and Conduct: In this study, patients were randomly divided into two groups A and B. Group A patients after skin biopsy as a donor site, in vitro melanocyte suspensions are prepared in accordance with patent procedures. The suspension obtained is transmitted to the desired area via dermabrasion technique. Group B patients receive suspension with Erbium YAG laser technique. From the third week UVA phototherapy is administered weekly for 3 months. Outcom measures will be assessed by the use of serial photography at baseline, one, three and six months after intervention. The study population: Post- burn leukoderma patients. Inclusion criteria: Age ≥ 18 years; without history of chronic diseases; The absence of coagulopathy; No evidence of hypertrophic burn scar; The total area treated is >40 cm². Exclusion criteria: Previous treatment of skin lesions; Active systemic infection. Intervention: One arm receives suspension via dermabrasion technique and the other receives suspension via Erbium YAG laser. Main Outcome Measures: Repigmentation scales assessed by dermatology Colleagues blinded to the randomization process and by means of serial photography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013026269N1**

Registration date: **2016-03-23, 1395/01/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-23, 1395/01/04

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ethics committee of Isfahan University of Medical Sciences

Expected recruitment start date

2015-06-05, 1394/03/15

Expected recruitment end date

2015-11-06, 1394/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Autologous melanocyte - keratinocyte suspension transplantation in patients with postburn leukoderma Comparison of two techniques to prepare the recipient site: Dermabrasion Versus Erbium: YAG laser

Public title

efficacy of skin pigment suspension in treatment of white burn scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age ≥ 18 years; Non-pregnant and non-breast feeding women; without history of chronic diseases, skin cancer, drug sensitivity/severe allergic reactions, immun deficient, organ transplant or steroid treatment; The absence of coagulopathy or anticoagulation therapy; No evidence of hypertrophic burn scar; The total area treated is >40 cm². Exclusion criteria: Previous treatment of skin lesions; Active systemic infection.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

City

Isfahan

Postal code**Approval date**

2015-05-27, 1394/03/06

Ethics committee reference number

IR.MUI.REC.1394.3.304

Health conditions studied**1****Description of health condition studied**

post-burn leukoderma

ICD-10 code

L81.5

ICD-10 code description

Leukoderma, not elsewhere classified

Primary outcomes**1****Description**

repigmentation scales

Timepoint

one, three and six months after the end of treatment

Method of measurement

by dermatology Colleagues blinded to the randomization

Secondary outcomes**1****Description**

Edema, Erythema, Infection and Dyspigmentation

Timepoint

One week, one month, three months and six months after treatment

Method of measurement

Eye Clinical Evaluation

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

After preparing melanocyte suspension according to patent No.139250140003003854, dermabrasion performed by high-speed motor dermabrator and Suspension will be transferred to the desired location. It is then covered by a mepitel bandage. Patients treated with oral antibiotics for a week (Cephalexin 500 mg Q6h). In the first follow-up a week later removed the bandage. From the third week UVA phototherapy is administered weekly for 3 months.

Category

Treatment - Devices

2**Description**

After preparing melanocyte suspension according to patent No.139250140003003854, Suspension by Erbium YAG laser (lotus II, laseropteck company, Seoul, Korea, 2012) with wave length 2940 nm, spot size 3 mm, pulse energy 1200 mj and 2 laser passes will be transferred to the desired location. It is then covered by a mepitel bandage. Patients treated with oral antibiotics for a week

(Cephalexin 500 mg Q6h). In the first follow-up a week later removed the bandage. From the third week UVA phototherapy is administered weekly for 3 months.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin disease and Leishmaniasis Research Center,
Isfahan University of Medical Sciences, Isfahan, Ira

Full name of responsible person

Dr Marzieh Matin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of
Medical Sciences.

Full name of responsible person

Dr Mansur Siavash

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Sciences, Hezar Jerib Avenue, Isfahan.

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Grant name

Grant code / Reference number

394304

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

Yes

Title of funding source

Vice Chancellor for research of Isfahan University of
Medical Sciences.

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

Skin disease and Leishmaniasis Research Center,

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

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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