Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Phase I/II clinical trial of melanocyte and keratinocyte transplantation in hypopigmented burn scar patches

Protocol summary

Study aim
Evaluation of the safety and efficacy of autologous melanocyte keratinocyte suspension transplantation on pigmentation of hypopigmented patches following burn scar

Design
Non-randomized, single center, open lable, phases I/II clinical trial

Settings and conduct
This study is performed in phases 1 and 2 in Hazrat Fatemeh Hospital. In phase 1, first 10 patients are included in the study and if no adverse events are observed, the second phase is performed with 30 patients. After local anesthesia, the skin sample is removed from the gluteal normopigmented skin using a manual dermatome. After isolation of keratinocytes and melanocytes, the cell suspension is transplanted to the hypopigmented area. Patients are then followed up for 6 months for probable side effects and repigmentation rate.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 12 to 65 years, Acute burn for more than 6 months ago; exclusion criteria: pregnancy or lactating, Infection in donor or reciept site, History of malignancy, Immuno-suppressive drugs in past 3 months

Intervention groups
Intervention group: Transplantation of autologous melanocyte and keratinocyte suspension to hypopigmented area; Control group: None

Main outcome variables
First endpoint: safety, second endpoint: repigmentation rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210612051545N1**
Registration date: **2021-06-16, 1400/03/26**
Registration timing: **prospective**

Last update: **2021-06-16, 1400/03/26**
Update count: **0**

Registration date
2021-06-16, 1400/03/26

Registrant information

Name
Amir Bajouri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Phase I/II clinical trial of melanocyte and keratinocyte transplantation in hypopigmented burn scar patches

Public title
Cell therapy in hypopigmented patches following burn scar

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 12 to 65 years Acute burn for more than 6 months ago
Exclusion criteria:
pregnancy or lactating Infection in donor or reciept site History of malignancy Immuno-suppressive drugs in past 3 months
Age
From **12 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
5th floor, Central office, Iran University of Medical Sciences, Hemmat Ave.
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Approval date
2021-05-10, 1400/02/20
Ethics committee reference number
IR.IUMS.REC.1400.155

Health conditions studied

1

Description of health condition studied
Burn scar
ICD-10 code
M61.3
ICD-10 code description
Calcification and ossification of muscles associated with burns

Primary outcomes

1

Description
safety of intervention method
Timepoint
1, 3, and 6 months after transplantation
Method of measurement
medical history and physical exam

Secondary outcomes

1

Description
Repigmentation rate
Timepoint
1, 3, and 6 months after transplantation
Method of measurement
Image J software

Intervention groups

1

Description
Intervention group: Autologous keratinocyte and melanocyte suspension, single dose, 10-15 x10(6) cells, transplantation following laser, Motahari hospital clean room
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Hospital
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after blinding the individuals
When the data will become available and for how long
6 months after publishing the manuscript
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
In order to analyze the data related to the study outcome
From where data/document is obtainable
Amir bajouri bajouri.md@gmail.com
What processes are involved for a request to access data/document
After reviewing in the Research Council of Iran University of Medical Sciences can be presented which usually takes 1 to 2 months.
Comments