

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 label, 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 recipient 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2221 2537

Email address

bajouri.md@gmail.com

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 recipient 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.

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

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

Full name of responsible person

Amir Bajouri

Street address

21th st., Asadabadi st.

City

Tehran

Province

Tehran

Postal code

۱۴۳۳۹۳۳۱۱۱

Phone

+98 21 8871 7272

Email

bajouri.md@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Noor Ahmad Latifi

Street address

21th st., Asadabadi st.

City

Tehran

Province

Tehran

Postal code

۱۴۳۳۹۳۳۱۱۱

Phone

+98 21 8871 7272

Email

dr.noorahmadlatifi@yahoo.com

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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Soheila Naderi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

Street address

21th st. Asadabadi st.

City

Tehran

Province

Tehran

Postal code

۱۴۳۳۹۳۳۱۱۱

Phone

+98 21 8871 7272

Email

soheila_naderi2@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Amir Bajouri

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biotechnology

Street address

21th st., Asadabadi st.

City

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Province

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۱۴۳۳۹۳۳۱۱۱

Phone

+98 21 8871 7272

Email

bajouri.md@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Soheila Naderi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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soheila_naderi2@yahoo.com

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