Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Safety and efficacy of allogeneic cultured keratinocyte sheet transplantation for healing of deep second degree burn wounds: clinical trial phase I

Protocol summary

Study aim

Determining the safety and effectiveness of allogeneic cultured keratinocyte sheets in the treatment of acute second degree acute burns

Design

In this single group, open-label clinical trial study, five patients will be enrolled in regular order according to standard protocols. The first patient will be monitored for one month, and if cell therapy is safe, the next patient will be Entered the study. Again, provided the treatment is safe during this period, the second and then the third patient will enter the study. In the absence of severe and life-threatening complications, subsequent patients will be included in the study.

Settings and conduct

Location: Operating room of Shahid Motahari Hospital in Tehran Preliminary laboratory tests are performed at Royan Research Institute and clinical and paraclinical tests are performed at Shahid Motahari Hospital.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 70 years with deep second-degree heat burns involving 25 to 40% of the body surface, if they express written consent to participate in the study and wish to attend regular treatment and follow-up courses, enter the study. Pregnant or breastfeeding patients, with uncontrolled underlying disease, requiring intensive care, or multiple traumas are not included in the study.

Intervention groups

Product type: Allogeneic keratinocyte sheet How to use: Allogeneic keratinocyte sheet transplant size 60cm2 Number of transplantation: 1 or 2 times

Main outcome variables

Evaluation of side effects, including short-term and long-term, systemic or local, severe or mild, and related and unrelated side effects of cell therapy at times 3, 7, 10, 14, 21, 28 days, and 3 and 6 months after intervention according to CTCAEV5 criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N31**
Registration date: **2022-04-23, 1401/02/03**
Registration timing: **prospective**

Last update: **2022-04-23, 1401/02/03**
Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of allogeneic cultured keratinocyte sheet transplantation for healing of deep second degree burn wounds: clinical trial phase I

Public title

Safety and efficacy of allogeneic cultured keratinocyte sheet transplantation for healing of deep second degree burn wounds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-70 years Acute second-degree heat burns involving 25-40% of the body surface Existence of at least one deep second-degree burn wound with 60 cm2 in area in the trunk or limbs (except the joints and arms & feet) in which tendons, blood vessels, or bone tissue is not exposed Declaration of written consent to participate in the study and willingness to attend regular treatment and follow-up courses

Exclusion criteria:

Chronic uncontrolled underlying disease (vascular disease, diabetes, malnutrition, hypertension, cardiovascular disease) Known underlying psychiatric illness Pregnancy or breastfeeding History of cancer or chemotherapy Infection with viral diseases (HCV, HBV, HIV) History of organ transplantation or blood transfusion History of taking immunosuppressive or cytotoxic drugs during the last 6 months Respiratory injury Requires special care Multiple trauma (fracture, or thoracic, abdominal, or CNS trauma)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

Not randomized

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

Research ethics committees of Royan institute-Academic center for education, culture and research

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Ghasem Soleymani Highway

City

Tehran

Province

Tehran

Postal code

1951883831

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.ACECR.ROYAN.REC.1400.165

Health conditions studied

1

Description of health condition studied

Acute second-degree burn wound on the upper limbs

ICD-10 code

T22.2

ICD-10 code description

Burn of second degree of shoulder and upper limb, except wrist and hand

2

Description of health condition studied

Acute second degree burn wound in trunk

ICD-10 code

T21.2

ICD-10 code description

Burn of second degree of trunk

3

Description of health condition studied

Acute second-degree burn wound on the lower limbs

ICD-10 code

T24.2

ICD-10 code description

Burn of second degree of lower limb, except ankle and foot

4

Description of health condition studied

Acute second degree burn wound involving 25-40% of body surface

ICD-10 code

T31.2

ICD-10 code description

Burns involving 20-29% of body surface

5

Description of health condition studied
Acute second degree burn wound involving 25-40% of body surface
ICD-10 code
T31.3
ICD-10 code description
Burns involving 30-39% of body surface

Primary outcomes

1

Description
No observed short-term or long term, systemic or local, severe or mild, and related or unrelated to cell therapy adverse effects
Timepoint
before the intervention, 3, 7, 10, 14, 21, 28 days, 3, and 6 months after the intervention
Method of measurement
CTCAEV5 methods

Secondary outcomes

1

Description
Duration of wound epithelialization
Timepoint
3, 7, 10, 14, 21, 28 days after intervention
Method of measurement
Solar calender

2

Description
Graft take rate
Timepoint
3, 7, 10, 14, 21, 28 days after intervention
Method of measurement
Physician evaluation

3

Description
Scar assessment
Timepoint
3 and 6 months after the intervention
Method of measurement
Based on Patient and Observer Scar Assessment Scale (POSAS) score

4

Description
scar assessment
Timepoint
3 and 6 months after the intervention
Method of measurement
Based on (VSS) Vancouver scar scale score

5

Description
Wound closure and scar shape
Timepoint
3, 7, 10, 14, 21, 28 days and 3 and 6 months after the intervention
Method of measurement
Based on 2D photography by Canon powershot S5Is

6

Description
Skin structure and quality improvement
Timepoint
6 months after the intervention
Method of measurement
Pathological criteria include H&E staining (hematoxylin and eosin), MT (Masson’s Trichrome), and immunohistochemistry (TGFβ-1,3, collagen 1,3 vimentin, α-SMA)

Intervention groups

1

Description
Intervention group: A deep second-degree burn wound of 60 cm2 in limbs or trunk (except joints, arms, legs, and areas where tendons, blood vessels, or bone tissue are exposed) will be selected. This area will be transplanted with an allogeneic keratinocyte sheet with an area of 60 square centimeters. If the wound does not heal on the tenth day, the transplant will be repeated.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Ensiyeh Hajizadeh Saffar
Street address
Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Resalat Highway
City
Tehran
Province
Tehran
Postal code
1665664511
Phone
+98 21 2233 9942
Email
hajizadeh.ehs@gmail.com

2

Recruitment center

Name of recruitment center
Shahid Motahari hospital

Full name of responsible person
Mostafa Dahmardehei

Street address
Shahid Motahari Hospital, Shahid Yasemi St, Vanak, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8877 0031

Email
m.dahmardei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
ATI tech pharmed

Full name of responsible person
Dr. Ensiyeh Hajizadeh Saffar

Street address
Golbarg alley. Royan alley. E Hafez St. Bani Hashem St. Resalat Highway

City
Tehran

Province
Tehran

Postal code
1665659911

Phone
+98 21 2233 9942

Email
hajizadeh.ehs@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
ATI tech pharmed

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Royan Institute

Full name of responsible person
Shayan Farzanbakhsh

Position
researcher

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Resalat Highway

City
Tehran

Province
Tehran

Postal code
1665664511

Phone
+98 21 2251 8388

Email
Shayan.farzanb@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Royan Institute

Full name of responsible person
Ensiyeh Hajizadeh Saffar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Biotechnology

Street address
Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Resalat Highway

City
Tehran

Province
Tehran

Postal code
1665664511

Phone
+98 21 2233 9942

Email
hajizadeh.ehs@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Royan Institute

Full name of responsible person
Hoda Madani

Position
researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Resalat Highway
City
Tehran
Province
Tehran
Postal code
1665664511
Phone
+98 21 2251 8388
Email
hoda62_m@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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