

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

according to CTCAEV5 criteria

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

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

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

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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 calendar

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

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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,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ATI tech pharmed

Full name of responsible person

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Associate professor

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Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for updating data

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Latest degree

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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

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