Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of the human acellular placental scaffold for treatment of superficial and deep second-degree burn wounds

Protocol summary

Study aim
The aim of this study was to clinically investigate the healing of superficial and deep second-degree burn wounds using a three-dimensional scaffold of acellular human placental tissue (decellularized placenta).

Design
The clinical trial has an experimental group and a control group, three blind strains randomized on 10 patients . A coin toss will be used for randomization.

Settings and conduct
The present study is conducted in Fatima Plastic and Reconstructive Surgery Hospital. This study aims to investigate the effectiveness and local safety of Placenta dressing in burn wound healing compared to a similar commercial dressing. The way of dressing the wound is that first the wound is washed with sterile distilled water and then it is covered with a dressing. The patient is not aware of the type of dressing used in each part of the wound, and the surgeon, nurse, and evaluating doctor are three different people.

Participants/Inclusion and exclusion criteria
Second-degree burn patients are selected from among those referred to the target hospitals. Inclusion criteria: Patients with skin wounds (burn trauma, diabetes, bedsores, etc.) after admission to the hospital. Exclusion criteria: Patients with the following criteria are excluded from the study: Pregnant and lactating women History of malignancy in wound healing The patient has taken suppressive drugs in the past three months

Intervention groups
Intervention group A: Placenta dressing. Intervention group B: wound dressing Agicoat

Main outcome variables
Rate and speed of recovery; pain; inflammation; wound size & fever

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230429058021N2**
Registration date: **2025-02-02, 1403/11/14**
Registration timing: **prospective**

Last update: **2025-02-02, 1403/11/14**
Update count: **0**

Registration date
2025-02-02, 1403/11/14

Registrant information

Name
Mazaher Gholipourmalekabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8670 4614

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-17, 1403/11/29

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the human acellular placental scaffold for treatment of superficial and deep second-degree burn wounds

Public title
Treatment of second-degree burn wounds using human placental tissue
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with superficial and deep second-degree burns with a burn area of at least 1%
Exclusion criteria:
Cases such as having severe vascular lesions, active or latent infection, or uncontrolled infection at the wound site can prevent the effectiveness of this allograft. Wound dressing derived placenta should not be used to treat lesions that do not have a definitive diagnosis. In patients with metabolic, heart, kidney, liver, blood, autoimmune or any other major diseases, this product should not be used without the permission of the attending physician.
Age
From **12 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
In each center, the samples are selected from consecutive patients using simple randomization method (tossing a coin). After that, the background characteristics of the patients in each group are evaluated.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient is unaware of the type of dressing used in each part of the wound, that is, he does not know which dressing is the main group and which is the control group. On the other hand, the surgeon who performs the dressing, the experienced nurse who records the history, and the doctor who evaluates the treatment result are three separate people. In this way, photos and histories are prepared and coded according to the checklist of the intervention and wound control parts at the designated times by the nurse (who is independent from the dressing and evaluator) and the photos are taken by the evaluating doctor who is from The type of dressing used in each photo is unknown, it is checked and the results are recorded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Burn research center of Fatima hospital
Street address
21st Street, Asadabadi St, Hazrat Fatima (PBUH) Educational and Medical Center, Yousef Abad , Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1433933111
Approval date
2024-02-05, 1402/11/16
Ethics committee reference number
IR.IUMS.REC.1402.1016

Health conditions studied

1

Description of health condition studied
Superficial and deep second-degree burn wounds
ICD-10 code
T21.2
ICD-10 code description
Burn of second degree of trunk

Primary outcomes

1

Description
Time and size (area) of the wound according to the CRF form
Timepoint
0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation
Method of measurement
Observation and measurement of wound area

2

Description
Redness
Timepoint
0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation
Method of measurement

Observation and examination of the patient by a specialist doctor

3

Description
Pain level according to the CRF form
Timepoint
0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation
Method of measurement
Examination of the patient by a specialist doctor

4

Description
Check the fever according to the CRF form
Timepoint
0, 3, 6, 9, 12, 15, 18 and 21 days after primary transplantation
Method of measurement
Thermometer

Secondary outcomes

1

Description
Wound healing time
Timepoint
Every 3 days to 21 days
Method of measurement
Patient examination and visual inspection

2

Description
Wound size
Timepoint
Every 3 days to 21 days
Method of measurement
Visual inspection and ruler

3

Description
Pain
Timepoint
Every 3 days to 21 days
Method of measurement
Patient examination

Intervention groups

1

Description
Intervention group: After selecting the patients and obtaining written consent from the patient or his/her legal guardian, the wound after washing with normal saline is covered with the placental scaffold. If necrosis or infection is observed, the scaffold should be removed and replaced as directed by the treating physician. Otherwise, it will remain in the wound until the final stage of healing.
Category
Treatment - Surgery

2

Description
Control group: After selecting the patients and obtaining written consent from the patient or his/her legal guardian, the wound after washing with normal saline is covered with the commercial wound dressing and three layers of sterile gauze are placed on it. If the wound has a lot of exudate, the dressing will be changed daily. In cases of less exudate, it is changed every three to five days
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari hospital
Full name of responsible person
Dr Tayyeb Ghadimi
Street address
No 3, Rashid Yasemi Ave, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mazaher Gholipourmalekabadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Person responsible for updating data

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

According to the CRF file, the obtained results, such as healing rate, wound size, redness, inflammation, fever, etc. during treatment are coded, and each code identifies the patient's personal information. The patient's personal information will only be available to

the project manager.

When the data will become available and for how long

The information that can be presented after the completion of the project and the analysis of the results will be presented in scientific journals or in the congress.

To whom data/document is available

Only respected project managers will have access to the results of the patient's personal information. The information of the results of the study will be available to all people without mentioning the patient in the form of a scientific article.

Under which criteria data/document could be used

The information of this study will also be provided to the Food and Drug department of Iran University of Medical Sciences or the medical equipment and supplies department of the Tehran Food and Drug Administration.

From where data/document is obtainable

Respected executors of the plan

What processes are involved for a request to access data/document

After the end of this project, the results of the study will be published as a scientific paper and available online. Although someone needs the results in more detail, he can request scientific data (not the patient's person) from the author of the article through the email provided in the section responsible for the article.

Comments