

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Design and evaluation of biological dressing efficiency with tissue engineering structure in wound healing of Epidermolysis bullosa patients: the first stage of phase 2

Protocol summary

Study aim

Design and evaluation of biological dressing efficiency with tissue engineering approach in wound healing of Epidermolysis bullosa patients: a pilot study

Design

Clinical trial with intervention group, community-based and pragmatic, with parallel, non-blind, non-random
Predicted sample size: 15; phase 2

Settings and conduct

This study will be performed in Imam Reza Hospital. For the first intervention group, adipose tissue stem cells will be placed on the amniotic scaffold and placed on the wounds created on the skin area. Also, for the second intervention group, keratinocytes will be placed on the scaffold and the healing effect of the wound will be investigated.

Participants/Inclusion and exclusion criteria

Entry requirements: Agreeing to participate in the study;
Lack of access to common dressings No entry:
Underlying disease; The unwillingness of the patient;
Infection

Intervention groups

1- Use of biological dressing of amniotic membrane as scaffold and keratinocyte cells 2- Using amniotic membrane dressing as a scaffold and adipose stem cells

Main outcome variables

Recovery time; The size of wound healing; Wound recurrence; Wound recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181222042074N2**
Registration date: **2022-06-29, 1401/04/08**
Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

Registration date

2022-06-29, 1401/04/08

Registrant information

Name

Shirin Toosi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

tusi1063@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation of biological dressing efficiency with tissue engineering structure in wound healing of Epidermolysis bullosa patients: the first stage of phase 2

Public title

Evaluation of the effect of amniotic scaffold and keratinocyte cells on wound healing from butterfly wing disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with a diagnosis of butterfly wing genetic disease
Agreeing with informed consent to participate in the study

Exclusion criteria:

Reluctance to cooperate Complications in wounds such as infections

Age

To 10 years old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

University St., Mashhad University of Medical Sciences (Qureshi) Office Building, Second Floor, Mashhad Vice Chancellor for Research

City

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Province

Razavi Khorasan

Postal code

9183773193

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.MUMS.REC.1401.043

Health conditions studied

1

Description of health condition studied

Epidermolysis bullosa

ICD-10 code

Q81

ICD-10 code description

Epidermolysis bullosa

Primary outcomes

1

Description

Wound healing rate

Timepoint

weekly

Method of measurement

Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Amniotic scaffold with adipose stem cells. Isolated samples are used for liposuction to extract MSCs. Tissue tissue is treated with type 2 collagenase enzyme and the working sample is incubated with type 2 collagenase enzyme in a 37°C shaker hot water bath for 1 hour. The container containing the 37°C water bath is transferred under the hood. To neutralize the effect of type 2 collagenase enzyme by adding serum-containing medium (FBS 10%) and transferring the mixture to 50 ml Falcons (the tissue is seen to be changed in a 1: 3 ratio with 10% FBS culture medium and then digested into falcons. 50 ml is transferred). The suspended cells, tissue and culture medium and DPBS in the 3 supernatants in the falcons are then removed using a 25 ml pipette and the Falcons containing the cell suspension are placed in a 400G centrifuge for 6 minutes to precipitate the cell. Take. they take. The next step was to discard the supernatant and dissolve the resulting cell sediment in MSC medium and pour the cells into T75 flasks and finally transfer the flasks to the incubator (one T75 flask was used for every 15 ml of primary fat sample). The obtained cells, after completely covering the surface of the flask, obtain a cell plate and then implant it on a scaffold made of amniotic membrane.

Category

Treatment - Devices

2

Description

Intervention group 2: Amniotic scaffold with keratinocyte cells. In this study of keratinocytes, skin samples from the abdomen or hypogastric area after liposuction

surgery or neonatal circumcision samples will be used. The received skin sample is transferred under the hood and the efficient part of the skin will be cut to 10 cm x 5 cm. It will then be rinsed 3 times in PBS solution (containing 2X Penicillin / Streptomycin) and then the skin pieces will be transferred into 7 ml of Dispase solution (10 mg / ml) containing 1X Penicillin / Streptomycin and the samples will be stored at 4 ° C. The temperature will be 17-18 hours. The sample is then trypsinized for 15 minutes and then the culture medium is pipetted with 10% FBS and the cells are separated using a 70 micron mesh filter and a 400 rpm centrifuge for 6 minutes. The complete culture medium is then transferred to the flask on the cell plate and the culture medium is changed every two days. After the cells have completely filled the surface of the flask, a cell plate is taken and the cells are implanted in the amniotic scaffold.

Category

Treatment - Devices

3

Description

Control group 1: Amniotic scaffold. Amniotic dressing will be purchased ready-made from manufacturers and the effectiveness of this cell-free scaffold in wound healing will be evaluated. Also, this type of dressing is now used to repair many cracks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Ahmad Shah Farhat

Street address

Imam Reza Square, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobarhan

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University St., Mashhad University of Medical Sciences (Qureshi) Office Building, Second Floor, Mashhad Vice Chancellor for Research

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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

Mashhad University of Medical Sciences

Proportion provided by this source

66

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

Mashhad University of Medical Sciences

Full name of responsible person

Shirin Toosi

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Person responsible for scientific inquiries

Contact

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Ahmad Shah Farhat

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Professor

Latest degree

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Person responsible for updating data

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Full name of responsible person

Shirin Toosi

Position

Researcher

Latest degree

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Other areas of specialty/work

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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