Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy and safety of amniotic membrane seeded by allogenic skin cells on chronic wound of patients with dystrophic epidermolysis bullosa; phase II randomized clinical trial

Protocol summary

Study aim

1- Evaluation of the safety and efficacy of amniotic membrane seeded by allogenic fibroblast and keratinocyte in chronic wounds of patients with dystrophic epidermolysis bullosa 2- comparison of the wound size, severity and recurrent rate in amniotic membrane seeded by allogenic fibroblast and keratinocyte group and amniotic membrane group 3- comparison of the expression of type 7 collagen in amniotic membrane seeded by allogenic fibroblast and keratinocyte group and amniotic membrane group

Design

Randomized, double blinded, controlled, parallel group phase II clinical trial in 20 patients and 6 months follow up

Settings and conduct

In each patient referred to the Skin and Stem Cell Center 2 wounds with 10 to 100 cm square are selected and then randomly covered by the amniotic membrane seeded by allogenic fibroblasts or amniotic membrane alone. The scaffold will be prepared every 4 weeks until complete wound closure. The wounds are evaluated each week for up to 1 month, and then every month, up to 6 months after transplantation, in terms of the severity and extent of the wound, the number of needed scaffolds, the relapse time, and the expression rate of collagen type 7.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20 patients aged 2-20 years old, Both sexes, Dystrophic type, Multiple skin wounds which are recurrent during 6 months ago Exclusion criteria: Pregnancy or lactating, Arterial or venous defects in recipient site, Immune deficiency, Hemolytic anemia, Chronic malnutrition, Respiratory defects, Diabetes, Local infection of recipient site, Cell transplantation of recipient site during last 1 year, HBV, HCV, and HIV, Malignancy of recipient site

Intervention groups

Amniotic membrane seeded by allogenic skin cells group
Amniotic membrane group

Main outcome variables

Wound size, complete wound closure, wound severity, pain intensity, collagen type 7 expression rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001159N20**
Registration date: **2018-05-04, 1397/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-04, 1397/02/14**
Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name
Mohamad Ali Nilforoushzadeh
Name of organization / entity
Skin and Stem Cell Research Center, Tehran University of Medical sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of amniotic membrane seeded by allogenic skin cells on chronic wound of patients with dystrophic epidermolysis bullosa; phase II randomized clinical trial

Public title

Effects of cell therapy in treatment of epidermolysis bullosa

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with 2-20 years old Both sexes Dystrophic type of EB Multiple skin wounds which are recurrent during 6 months ago

Exclusion criteria:

Pregnancy or lactating Arterial or venous defects in recipient site Immune defficiency Hemolytic anemia Chronic malnutrition Respiratory system defects Diabetes Local infection of recipient site Cell transplantation of recipient site during last 1 year HBV, HCV, and HIV infection Any malignancy of recipient site

Age

From **2 years** old to **20 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple Randomization unit: Individual stratified randomization is not included Randomization Tool: Random number box Allocation concealment: The cell product and placebo are delivered to the physician with code numbers. Then the dressings will be placed on the patient's wound based on randomization number box.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, researchers, health care persons including its physician and nurse, and the outcome evaluator are blinded until the end of study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz st, Qods st, Central building of university, 6th floor, deputy for research and technology

City

Tehran

Province

Tehran

Postal code

1416613675

Approval date

2018-01-01, 1396/10/11

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4099

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 extent (cm2)

Timepoint

Before intervention, every week up to 1 month, and every month up to 6 months

Method of measurement

Image J software

Secondary outcomes

1

Description

Safety
Timepoint
intervention start date up to 6 months
Method of measurement
Medical history and physical examination

Intervention groups

1

Description
Intervention group: Amniotic membrane seeded by allogenic fibroblast
Category
Treatment - Other

2

Description
Control group: amniotic membrane
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin and Stem cell Research Center
Full name of responsible person
Mohammad Ali Nilforooshzadeh
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Maryam alley, Pasha Zahari st, South Kamranieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Web page address
http://skinstemcell.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Iranian academic center for education culture and research
Full name of responsible person
Amir Bajouri
Position
Clinical researcher
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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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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

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 will be shared after unidentifiable of the patients

When the data will become available and for how long

6 months after paper publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

In term of analysis the data related to study outcomes

From where data/document is obtainable

bajouri_md@yahoo.com

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

The request will be assessed by research committee of Skin and Stem cells research center which will be taken around 1-2 months

Comments