

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy of transplantation of autologous cultured fibroblast on amniotic membrane for treatment of epidermolysis bullosa patients with mitten hand deformity after hand surgery phase 1

Protocol summary

Study aim

Evaluation of safety and efficacy of autologous transplantation of cultured fibroblast on amniotic membrane (AM, as coverage) for healing of mitten hands

Design

A clinical trial, uncontrolled, unblinded and not randomized on 20 patients

Settings and conduct

EB patients with mitten hands deformity of who willing to recruit to this study attended to the Hazrat-e-Fateme Hospital, Tehran, Iran, or the Dermatology Clinic of Cell Therapy Center at Royan Institute, Tehran, Iran. When the consent form was accepted and the lab test was confirmed, a small skin biopsy was removed from retro auricle and fibroblast cells were separated and cultured. These cells were seeded on AM and the microbial test was done as evidence to prove the safety. Under general anesthesia, when the hands adhesion was removed, the autologous fibroblast cultured on AM was transplanted to the both hands and the hands were dressed afterward.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both genders, Age: 2-30y, No history of other systemic disease, No history of other cell therapy method, No infection in donor or recipient site. Exclusion Criteria: Age less than 2y or more than 30y, History of other systemic disease, History of other cell therapy method, Infection in donor or recipient site positive, Lab tests for contagious viral diseases, Pregnancy or lactating History of malignancy.

Intervention groups

Biological: cell transplantation autologous transplantation of cultured fibroblast on amniotic membrane in patients with Epidermolysis Bullosa with mitten hands.

Main outcome variables

Evaluation of adverse event after transplantation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N28**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **retrospective**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

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

2010-04-19, 1389/01/30

Expected recruitment end date

2012-09-01, 1391/06/11

Actual recruitment start date

2010-07-01, 1389/04/10

Actual recruitment end date

2012-12-01, 1391/09/11

Trial completion date

2013-12-06, 1392/09/15

Scientific title

Safety and efficacy of transplantation of autologous cultured fibroblast on amniotic membrane for treatment of epidermolysis bullosa patients with mitten hand deformity after hand surgery phase 1

Public title

Evaluation of transplantation of autologous cultured fibroblast on amniotic membrane for treatment of epidermolysis bullosa patients with mitten hand deformity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Epidermolysis Bullosa patients with mitten hand deformity Patients with 2 to 30 years old

Exclusion criteria:

History of other systemic disease History of other cell therapy method Infection in donor or recipient Site Positive Lab tests for contagious viral diseases Pregnancy or lactating

Age

From **2 years** old to **30 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **12**

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

Royan Institute Ethics Committee

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Ghasem Soleymani highway

City

Tehran

Province

Tehran

Postal code

1665664511

Approval date

2012-09-27, 1391/07/06

Ethics committee reference number

EC /91/1082

Health conditions studied

1

Description of health condition studied

Epidermolysis Bullosa patients with mitten hand deformity

ICD-10 code

Q81.2

ICD-10 code description

Epidermolysis bullosa dystrophica

Primary outcomes

1

Description

Safety assessment of autologous transplantation of cultured fibroblast on amniotic membrane for healing of mitten hands.

Timepoint

Patients' dressings were changed every 7 days until the wound was completely healed. Then the visits were done in 3, 6, 12 months and then annually.

Method of measurement

Physical examination

2

Description

Histological evaluation of autologous transplantation of cultured fibroblast on amniotic membrane for healing of mitten hands.

Timepoint

6 month after transplantation

Method of measurement

Biopsy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transplantation of autologous cultured Fibroblast on amniotic membrane for treatment of epidermolysis bullosa patients with mitten hand deformity

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Dr. Nasser Aghdami

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Abdolhossein Shahverdi

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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

Royan Institute

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

Royan Institute

Full name of responsible person

Hoda Maadani

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Web page address**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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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