Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effectiveness of Cord Blood Platelet Gel (CBPG) for treatment of Epidermolysis Bullosa (EB) ulcers

Protocol summary

Study aim

Study of the effectiveness of Cord Blood Platelet Gel (CBPG) for treatment of Epidermolysis Bullosa (EB) ulcers

Design

In this study, 15 patients were matched with EB patients' home . The size of the wound caused by EB ,should be on the hand is more than 10 and less than 20 cm*cm. In this intervention, one of the wound EB treat with new dressing (paletlet gel from the cord blood) and another wound on the hand patient is compared with routine treatment at the same time. This intervention is the third phase of the trial. In this intervention, three dressings in three times are performed for each patient at intervals on the other days

Settings and conduct

The location of intervention is in the EB patients' home. In this study blindness was not made and all patients and physicians are aware of the type and wound dressing structure.

Participants/Inclusion and exclusion criteria

Inclusion criteria - -The wound should be on the hand. Both of genders can be entered this study. -The surface of ulcer should be more than 10 and less than 20 cm2. Exclusion Criteria -The patients that have specially diseases such as diabetes , allergy and coagulation of blood. -The wound that has a very low or high expansion

Intervention groups

The intervention group consists of people who have wound of EB with the entry conditions mentioned above and receive the desired dressing (platelet gel derived from umbilical cord blood), and the control group is also the same as those who are involved in biological dressing intervention have participated in the routine treatment of EB wounds.The control section is commonly used, including dressing and using silver sulfadiazine, and the intervention section, in addition to the routine treatment, will receive the platelet gel product,

Main outcome variables

- Evaluation the amount of effectiveness platelet gel derived cord blood on the treatment wound of EB

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141007019432N5**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **prospective**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date

2018-02-21, 1396/12/02

Registrant information

Name

Mohammadamir Amirkhani

Name of organization / entity

Skin and Stem Cell Research Center, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-20, 1397/03/30

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of Cord Blood Platelet Gel (CBPG) for treatment of Epidermolysis Bullosa (EB) ulcers

Public title

Study of the effectiveness of Cord Blood Platelet Gel (CBPG) for treatment of Epidermolysis Bullosa (EB) ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The wound of EB should be on the hand The patients that have EB Both of genders can be entered this study. The surface of wound should be more than 10 cm2 and less than 20 cm2

Exclusion criteria:

The patients that they have some diseases such as diabetes ,allergy and coagulation of blood . The wound of EB that has a very low or high expansion .

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **3**

platelet derived cord blood are used topically for each person 3 times(every other days),

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

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 Medical Sience

Street address

Tehran University of Medical Sciences, Cross Qods st, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-12-19, 1396/09/28

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4285

Health conditions studied

1

Description of health condition studied

Wound and Epidermolysis Bullosa

ICD-10 code

Q81

ICD-10 code description

Epidermolysis bullosa

Primary outcomes

1

Description

Formation of wound granulation tissue .

Timepoint

Before intervention and 6 day after the last intervention

Method of measurement

the wound is examined by the pictzar software

2

Description

reduction wound surface and deep

Timepoint

Before intervention and 6 day after the last intervention

Method of measurement

Surface and deep of the wound are examined by the pictzar software

Secondary outcomes

1

Description

Pain from the wound of EB

Timepoint

6 days after the first intervention

Method of measurement

Question and answer from patient.

Intervention groups

1

Description

Intervention group:Including persons who have EB wound

on their hands larger than 10 and less than 20 cm2

Category

N/A

2

Description

Control group: At the same time, the same group of patients who have another wound on their hands receive dressing including routine treatment (without the use of a platelet gel derived from umbilical cord blood).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin & Stem Cell Research Center of Medical Tehran University

Full name of responsible person

Mohammad Amir Amirkhani

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Thran -Iran Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Presidency for Science and Technology

Full name of responsible person

Alireza Sadeghi

Street address

Vice Presidency for Science and Technology complex , Ladan alley , North shiraz street , Molasadra street

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Grant name

Vice Presidency for Science and Technology

Grant code / Reference number

1595

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Presidency for Science and Technology

Proportion provided by this source

50

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Amir Amirkhani

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Skin & Stem Cell

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Mohammadali Nilforoushzadeh

Position

Professor & Head of the Skin & Stem Cell Center

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Master of science in biotechnology

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Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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
No - There is not a plan to make this available