

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of adding cord blood platelet gel (CBPG) to the standard treatment on granulation tissue formation and time of wound healing in second degree burn ulcer

Protocol summary

Study aim

Assessing the effectiveness of platelet gel derived cord blood on the treatment burn of ulcer

Design

In this trial, 15 patients were invited to participate in this study from Motahari burning Hospital. The size of the wound caused by burn that should be on the hand is more than 10 and less than 20 cm². In this intervention, the wound with the desired dressing (platelet gel from the cord blood) with another wound on the hand of the same patient is compared with routine treatment at the same time. This is a phase III 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 Motahari burning hospital. 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 -Patients that have burn ulcer should be they average age between 20 to 40 years. -The burn of ulcer should be on the hand. -The burn of ulcer should be second degree and deeply. -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. - If the burn of ulcers are one or three degree. -The burn of ulcer that has a very low or high expansion.

Intervention groups

The intervention group consists of people who have burn ulcers 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

burn ulcers. 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

Surface area of granulation tissue, healing time, and surface area of the wound

General information

Reason for update

Acronym

CBPG (Cord Blood Platelet Gel)

IRCT registration information

IRCT registration number: **IRCT20141007019432N4**

Registration date: **2018-01-16, 1396/10/26**

Registration timing: **prospective**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

Registration date

2018-01-16, 1396/10/26

Registrant information

Name

Mohammad Amir 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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

2018-03-11, 1396/12/20

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

empty

Scientific title

Comparing the effect of adding cord blood platelet gel (CBPG) to the standard treatment on granulation tissue formation and time of wound healing in second degree burn ulcer

Public title

Production of Cord Blood Platelet Gel (CBPG) for treatment of burn ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients that have second degree burn of ulcer Age between 20 to 40 years The burn of ulcer should be on the hand. The burn of ulcer should be second degree and deep. Both of genders can be entered this study. The surface of ulcer 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 coagulopathy If the burns of ulcers are first or third degree The burn of ulcer that has a very low or high surface area

AgeFrom **20 years** old to **40 years** old**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: **2**

Each person should have two areas of burn ulcer on his/her hands. one area will receive the first intervention and the other one will receive the second intervention

Actual sample size reached: **10**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Each person should have two areas of burn ulcer on his/her hands. one area will receive the first intervention and the other one will receive the second intervention

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 Science

Street address

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

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-11-06, 1396/08/15

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3887

Health conditions studied**1****Description of health condition studied**

burn and ulcer

ICD-10 code

T23.2

ICD-10 code description

Burn of second degree of wrist and hand

Primary outcomes**1****Description**

Area of granulation tissue formation

Timepoint

before intervention and 6 days after last intervention

Method of measurement

pictzar software

2**Description**

Area and depth of the wound

Timepoint

before intervention and 6 days after last intervention

Method of measurement

pictzar software

Secondary outcomes

1

Description

Pain from the burn of ulcer

Timepoint

6 days after the first intervention

Method of measurement

Question and answer from the patient

Intervention groups

1

Description

Intervention group: Including persons who have burn of ulcers on their hands larger than 10 and less than 20 cm², aged between 20 until 40 years old and their burn ulcer is classified as second degree and deep

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 Tehran University and

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

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Grant name

Vice Presidency for Science and Technology

Grant code / Reference number

2901

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

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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

No - There is not a plan to make this available