Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (paletlet 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 tine, 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

Mohammadamir Amirkhani

Name of organization / entity

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

Country

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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
Age
From **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 recieve the first intervention and the other one will recieve 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 recieve the first intervention and the other one will recieve 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 Sience
Street address
Tehran University of Medical Sciences, Cross Qods st, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-11-06, 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 to 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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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
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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