

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Apr 2019

### Application of Cord Blood Platelet Gel (CBPG) for treatment of skin ulcers due to cutaneous chronic GVHD

#### Protocol summary

##### Study aim

the effectiveness of platelet gel derived from cord blood on the GVHD wound treatment.

##### Design

In this study, there are two groups (intervention and control) that are examined simultaneously is one patient and 15 patients are matched with children's medical center hospital. This intervention is the third phase of the trial. In this intervention, dressings are performed in three times for each patient which are changed on the other days.

##### Settings and conduct

The location of intervention is in the children 's medical center 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

The wound should be on the hand.The wound must be second degree ,Both of genders can be entered this study.The size of wound should be more than 5 cm<sup>2</sup> and less than 10 cm<sup>2</sup> ,exclusion criteria :The patients with other diseases such as diabetes, allergy and coagulopathy

##### Intervention groups

The intervention group consists of people who have wound of GVHD who meet the inclusion criteria mentioned above and receive the desired dressing (platelet gel derived from umbilical cord blood). The control group is also the same persons in the intervention group and receive routine treatment on the other wound caused by GVHD. The size of the wound caused by GVHD ,should be more than 5 and less than10 cm\*cm on the hand.

##### Main outcome variables

The effectiveness of platelet gel derived from cord blood on the GVHD wound treatment.

#### General information

##### Acronym

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##### IRCT registration information

IRCT registration number: **IRCT20141007019432N6**  
Registration date: **2018-04-27, 1397/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-14, 1397/11/25**

Update count: **1**

##### Registration date

2018-04-27, 1397/02/07

##### Registrant information

###### Name

Mohammad Amirkhani

###### Name of organization / entity

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

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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

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Application of Cord Blood Platelet Gel (CBPG) for treatment of skin ulcers due to cutaneous chronic GVHD

##### Public title

Application of Cord Blood Platelet Gel (CBPG) for treatment of skin ulcers due to cutaneous chronic GVHD

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

The wound should be on the hand. The wound that have

second degree Both of genders can be entered this study. The surface of wound should be more than 5 cm<sup>2</sup> and less than 10cm<sup>2</sup>

**Exclusion criteria:**

The patients with other systemic diseases such as diabetes, allergy and coagulopathy

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

None

**Sample size**

Target sample size: **10**

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:

**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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**Postal code**

1417653761

**Approval date**

2017-12-19, 1396/09/28

**Ethics committee reference number**

IR.TUMS.VCR.REC.1396.4286

**Health conditions studied**

**1**

**Description of health condition studied**

Wound and GVHD

**ICD-10 code**

D89.81

**ICD-10 code description**

Graft-versus-host disease

**Primary outcomes**

**1**

**Description**

Formation of wound granulation tissue

**Timepoint**

before intervention and 6 days after last intervention

**Method of measurement**

Pictzar Software

**2**

**Description**

Reduction of wound area and depth

**Timepoint**

Before intervention and 6 day after the last intervention

**Method of measurement**

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

**Secondary outcomes**

**1**

**Description**

wound pain

**Timepoint**

6 days after the first intervention

**Method of measurement**

Question and answer from the patient

**Intervention groups**

**1**

**Description**

Intervention group: in this study, 15 patients are selected from children's medical center hospital. The size of the wound caused by GVHD, should be more than 5 and less than 10 cm\*cm on the hand. One of the wounds of GVHD is treated with new dressing (paletlet gel from the cord blood) and another wound of the same patient (on the hand) is treated with routine treatment at the same time. In this intervention, three dressings in three times are performed for each patient every other days.

**Category**

N/A

**2****Description**

Control group: At the same time, the same patients who have another wound on their hands receive dressing including routine treatment (in this group platelet gel derived from umbilical cord blood don't used).

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Skin & Stem Cell Research Center of Tehran University

**Full name of responsible person**

Mohammad Amir Amirkhani

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

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**Web page address****Grant name**

Skin & Stem Cell Research Center of Tehran Medical Science University

**Grant code / Reference number**

Non grant code

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

No

**Title of funding source**

Skin & Stem Cell Research Center of Tehran Medical Science University

**Proportion provided by this source**

30

**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**

Skin & Stem Cell Research Center of Tehran Medical Science

**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**

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**Full name of responsible person**

Dr. Amirali Hamidieh

**Position**

Associate professor.Stem Cell and Technology  
Development

**Latest degree**

Specialist

**Other areas of specialty/work**

Hematology and Oncology Stem Cell Transplantation

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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**

Undecided - It is not yet known if there will be a plan to  
make this available

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Alireza Shoaehassani

**Position**

PhD of Applied Cell Scieances

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Applied Cell Scieances

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