

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 cm² and less than 10 cm² ,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

--

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 1710

Email address

amirkhani@health.gov.ir

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 cm² and less than 10cm²

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

City

Tehran

Province

Tehran

Country

Iran (Islamic Republic of)

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 days 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

Street address

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

City

Tehran

Province

Tehran

Country

Iran (Islamic Republic of)

Postal code

1937957511

Phone

+98 21 2220 1710

Email

Amirkhani2000@yahoo.com

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

Tehran University of Medical Sciences

Full name of responsible person

Prof. Mohammadali Nilforoushzadeh

Street address

Street address Skin & Stem Cell Research Center, Maryam aley, South kamraneye, Tehran, Iran

City

Tehran

Province

Tehran

Country

Iran (Islamic Republic of)

Postal code

1937957511

Phone

+98 21 2220 1710

Fax

+98 21 2220 1710

Email

dr_nilforoush@yahoo.com

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

Street address

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

City

Tehran

Province

Tehran

Country

Iran (Islamic Republic of)

Postal code

1937957511

Phone

+98 21 2220 1710

Email

Amirkhani2000@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

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

Street address

Gharib street children's Medical Center of Imam
khomeiny Hospital Tehran Iran

City

Tehran

Province

Tehran

Country

Iran (Islamic Republic of)

Postal code

1937957511

Phone

+98 912 159 3270

Fax**Email**

aahamidieh@tums.ac.ir

No 132 - Gandhi st - Vanak

City

Tehran

Province

Tehran

Country

Iran (Islamic Republic of)

Postal code

1516748611

Phone

+98 21 8819 6540

Email

cell.therapy@yahoo.com

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

Street address