Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Safety and Effectiveness evaluation of Allogeneic Cord Blood Platelet Gel (CBPG) for the treatment of non-healing skin ulcers/erosion due to the cutaneous chronic GVHD: A Randomize Clinical Trial (Pilot study)

Protocol summary

Study aim

Finding early evidence of the safety and efficacy of using allogeneic cord blood platelet gel in the treatment of unhealed wounds in patients with chronic GvHD

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, phase 1 is performed on 15 patients, enrolled between July 2020 and July 2021.

Settings and conduct

This randomized clinical trial is performed at the Pediatric Cell Therapy Research Center located in the Children Medical Center affiliated to the Tehran University of Medical Sciences. In the intervention area the platelet, gels are prescribed up to 6 times every 5 days for each patient and if after this number of treatments up to 50% improvement is not achieved, it is classified as non-respondent. Samples are taken from the corners of the wounds and tissue granulation is examined in a pathology laboratory. The surface of the wounds is imaged and its reduction is examined. All patients will be evaluated for wounds changes after 1, 3, and 6 months and follow-up continues until the end of 6 months after the intervention. Patients will be evaluated by direct observation of wounds, wound imaging, wound surface area, and depth and sampling to examine tissue granulation.

Participants/Inclusion and exclusion criteria

Existence of chronic GvHD criteria after allogeneic hematopoietic stem cell transplantation

Intervention groups

The control area will receive the usual treatment, which includes dressing and using Vaseline and mupirocin antibiotic ointment, and the intervention area will receive the platelet gel product. Gels are prescribed up to 6 times every 5 days for each patient.

Main outcome variables

It will involve wound healing, unchanging, and ultimately wound healing. Reducing the patient's pain is also considered as an initial consequence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190101042197N1**
Registration date: **2020-08-24, 1399/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**
Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name
Alireza Shoae-Hassani
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and Effectiveness evaluation of Allogeneic Cord Blood Platelet Gel (CBPG) for the treatment of non-healing skin ulcers/erosion due to the cutaneous chronic GVHD: A Randomize Clinical Trial (Pilot study)

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of chronic GvHD criteria after allogeneic hematopoietic stem cell transplantation Wounds in the upper, lower and trunk Wound surface area more than 2 cm2 and less than 5 cm2 with at least 6 weeks durability Wound grading is 2 and 3. Minimum age one year and maximum 15 years

Exclusion criteria:

Other diseases such as diabetes, allergies, coagulopathies or underlying diseases that involve the skin Wounds are small (less than 1 cm) or very large (more than 5 cm) Wound grade is 1 or 4. Lesions on the face and neck

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Stratified Block Randomization method is used for randomization in the intervention and control groups. Since patients with different intensities are in the study, to ensure the equality of the number of people assigned to the two groups, the block randomization method is used in each category. Also, the blocks used are of sizes 2 and 4, and based on the sample size of 15 and the probable number of participants in the study with any severity of the disease, blocks with the appropriate volume are used to generate random codes. In order to place patients in control and intervention groups, a random sequence table is created with the SAS 9.1 software.

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 in Research of Children's Medical Center-Tehran University of Medical Sciences

Street address

Childrens Medical Center, Gharib Ave, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.TUMS.CHMC.REC.1399.072

Health conditions studied

1

Description of health condition studied

Unhealed skin ulcers in patients with chronic GVHD skin complications

ICD-10 code

D89.811

ICD-10 code description

Chronic graft-versus-host disease

Primary outcomes

1

Description

Reduce wound surface area

Timepoint

At the beginning of the study and 7, 15 and 30 days after the start

Method of measurement

Direct view

2

Description

Causes severe allergic reactions

Timepoint

1, 3 and 7 days after the intervention

Method of measurement

Direct view

3

Description
Infection
Timepoint
One week after intervention
Method of measurement
Sampling

4

Description
Reduced pain
Timepoint
One month after intervention
Method of measurement
direct examination

Secondary outcomes

1

Description
Normal physical activity
Timepoint
6 month after intervention
Method of measurement
Direct examination and observation

Intervention groups

1

Description
Intervention group: Platelet gel from allogeneic cord blood. Cord blood is taken from the umbilical cord blood bank of Bon Yakhte Royan Co. and then in the clean room of the Pediatric Cell Therapy Research Center, platelet gel is prepared from it. The gels are administered up to 6 times every 5 days for each patient with chronic GvHD skin ulcer and are classified as non-responder if no improvement of up to 50% is achieved after this number of treatments. Samples are taken from the corners of the wounds and tissue granulation is examined in a pathology laboratory. The surface of the wounds is imaged and its reduction is examined.
Category
Treatment - Other

2

Description
Control group: The wounds of the control group will be dressed in sterile conditions using Vaseline gas after washing.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center Hospital
Full name of responsible person
Maryam Behfar
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Children's Medical Center Hospital, Gharib Ave, Keshavarz Blvd, Tehran
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Sponsors / Funding sources

1

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+98 21 8978 1307
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Web page address
https://www.rsct.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Royan Stem cell Technology Co.
Proportion provided by this source
60
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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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 more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
Some data, such as information about the main outcome or the like, can be shared.
When the data will become available and for how long
Start of the access period one year after results publication.
To whom data/document is available
All
Under which criteria data/document could be used
There will be no limitation
From where data/document is obtainable
rashin_mohseni@yahoo.com
What processes are involved for a request to access data/document
primary evaluation and sending data
Comments