

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 Shoaee-Hassani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8877 0031

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alirezashoaee@gmail.com

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

Street address

Children's Medical Center Hospital, Gharib Ave, Keshavarz Blvd, Tehran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Royan Stem cell Technology Co.

Full name of responsible person

Morteza Zarrabi

Street address

No 24, East Hafez Alley, Bani Hashem Sq, Resalat Ave, Tehran

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Email

crm@rsct.ir

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

Dr. Rashin Mohseni

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell therapy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Amir Ali Hamidieh

Position

Professor

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Subspecialist

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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

