Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Characterization and evaluation of the safety and effectiveness of human umbilical cord blood serum alginate hydrogel on patients with 2A degree burns(Phase 1 clinical trial)

Protocol summary

Study aim

Characterization and evaluation of the effectiveness of umbilical cord blood serum alginate hydrogel on 2A degree burns

Design

This study is a phase 1 clinical trial, in which 30 qualified 2A degree burn wound samples from patients of Motahari Hospital were selected as research samples and randomly and without blinding were divided into two intervention and control groups of 15 people. The intervention group was treated with umbilical cord blood serum alginate hydrogel with a diameter of 5 mm on the burn wound, and the control group was treated with a layer of 1% silver sulfadiazine ointment along with a simple hydrogel dressing every other day for 14 days. At the arrival of the patient before the study and during the treatment on the 7th and 14th days, the speed of wound healing with Image J software and checking the amount of scar is the amount of pain reduction in the follow-up visits with photos and analysis and a questionnaire

Settings and conduct

The intervention group will be treated with umbilical cord blood serum alginate hydrogel with a diameter of 5 mm on the intended burn wound and the control group will be treated with a layer of 1% silver sulfadiazine ointment along with a simple hydrogel wound dressing every other day for 14 days in Motahari Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: men and women aged 18 to 60 years with 2A degree burns Exclusion criteria: the person has underlying infections and diseases and immune system deficiency. The wound is in the face and genital area

Intervention groups

The patients are divided into two intervention and control groups of 15 people, the intervention group is dressed with umbilical cord blood serum alginate hydrogel and the control group is dressed with 1% silver sulfadiazine ointment along with a simple hydrogel dressing

Main outcome variables

Healing time; scar rate; The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221130056672N3**
Registration date: **2024-01-10, 1402/10/20**
Registration timing: **prospective**

Last update: **2024-01-10, 1402/10/20**
Update count: **0**

Registration date

2024-01-10, 1402/10/20

Registrant information

Name

EHSAN Taghiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7541

Email address

etaghiabadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Characterization and evaluation of the safety and effectiveness of human umbilical cord blood serum alginate hydrogel on patients with 2A degree burns(Phase 1 clinical trial)

Public title

Characterization and evaluation of the safety and effectiveness of human umbilical cord blood serum alginate hydrogel on patients with 2A degree burns.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women aged 18 to 60 who have 2A degree burns with a burn percentage of less than 15% of the body surface. The dimensions of the burn wound should be 10 x 10 cm. Willingness to participate in research and able to answer questions.

Exclusion criteria:

Have underlying diseases and immune system defects such as diabetes, cancer, AIDS, high blood pressure and skin allergies. Before entering the sample into the research, they have used a substance other than drinking water on the wound. A person with symptomatic infection in different parts of the body. Burns in the face and genital area. More than 48 hours have passed from the time of the burn to the time of entering the study. According to the doctor's opinion, the person needs to be hospitalized.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple randomization method, patients who come to Motahari Hospital with 2A degree burns are placed in 2 groups of 15 people, so that one envelope is randomly selected for each patient from the number of 30 sealed envelopes. The letters A and B are inserted inside each envelope. Group A patients will be treated with 1% silver sulfadiazine ointment and group B will be treated with cord blood serum alginate hydrogel.

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

Research Ethics Committees of Research Institute for Oncology, Hematology and Cell Therapy - Tehran

Street address

Shariati Hospital, North Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2023-12-13, 1402/09/22

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1402.053

Health conditions studied

1

Description of health condition studied

2A degree burns

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Healing time

Timepoint

Measurement of healing time on days 0 (before the intervention), 7 and 14

Method of measurement

Photography with Image J software

Secondary outcomes

1

Description

The amount of pain

Timepoint

Pain measurement on days 0 (before the start of the intervention), 7 and 14

Method of measurement
questionnaire survey (Patient self-report)

Intervention groups

1

Description
Intervention group: Treated with human cord blood serum alginate hydrogel is placed as a layer with a diameter of 5 mm on the 2A degree burn wound and it is bandaged every other day for up to 14 days.
Category
Treatment - Other

2

Description
Control group: Treated with 1% silver sulfadiazine ointment along with a simple hydrogel dressing that is bandaged every other day for up to 14 days.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Hospital
Full name of responsible person
Mostafa Dahmardehei
Street address
Motahari Hospital, Rashid Yasemi St, Vanak Sq, Vali-e-Asr Ave, Tehran
City
Tehran
Province
Tehran
Postal code
1996714353
Phone
+98 21 8877 0031
Fax
+98 21 8877 0048
Email
motahari.hos@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Street address
Research and Technology Deputy, 6th floor, Quds St, Tehran University of Medical Sciences
City
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1937957511
Phone
+98 21 2665 7438
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etaghiabadi@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
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
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Taghiabadi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
No. 4 , 4th floor, Maryam dead end, South Kamraniyeh
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after de-identifying individuals.

When the data will become available and for how long
Six months after the publication and printing of the article

To whom data/document is available
Academic researchers and experts

Under which criteria data/document could be used
In order to analyze the results of the study outcomes

From where data/document is obtainable
etaghiabadi@sina.tums.ac.ir

What processes are involved for a request to access data/document
It can be submitted after review by the Research Council of the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, which usually takes 2 to 3 months.

Comments