

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Efficacy evaluation of a collagen/PVA wound dressing containing hybrid curcumin/chitosan nanoparticles combined with mesenchymal stem cell condition medium in burn wound (clinical phase 1 & 2)

Protocol summary

2022-07-09, 1401/04/18

Study aim

Efficacy evaluation of a hydrogellic collagen/PVA wound dressing containing hybrid curcumin/chitosan nanoparticles combined with endometrial mesenchymal stem cell condition medium in burn wound (clinical phase 1 & 2)

Design

Clinical trial with one control group parallel with one intervention group, double-blind, randomized based on random number table, phase 1-2 on 20 burn patients

Settings and conduct

The research site is Motahari Burn Hospital and Skin and Stem Cell Research Center. Blinding will be performed in a way that the patient the caregiver are both unaware of type and structure of dressings.

Participants/Inclusion and exclusion criteria

Patients 18-50 years old with grade 2 burns

Intervention groups

_The intervention group includes 10 patients receiving wound dressing together with condition medium _control group receiving standard tretment

Main outcome variables

The amount of granulation tissue, the duration of wound healing, the area of wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220512054831N1**

Registration date: **2022-07-09, 1401/04/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-09, 1401/04/18**

Update count: **0**

Registration date

Registrant information

Name

Reza Naser

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2245 4327

Email address

rnit101@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of a collagen/PVA wound dressing containing hybrid curcumin/chitosan nanoparticles combined with mesenchymal stem cell condition medium in burn wound (clinical phase 1 & 2)

Public title

combined efficacy of wound dressing and mesenchymal condition medium on burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
second degree burn

Exclusion criteria:
Immune disorders, malignancy and underlying conditions such as type 1 diabetes

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method using a random number table will be applied. Each patient receives a code between 01 and 20 respectively right after registration. The researcher receives the numbers and randomly starts from one point on the table and proceeds until the the first number with digits between 01 to 20 on the right is seen. This code corresponds to one of the patients and this process repeats until our control group is completed. After that, the 10 remaining patients are categorized as intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to make the process blind for clinical operator; packages of wound dressings will be designed with identical shapes and with similar contents which will be indistinguishable.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd

City

Tehran

Province

Tehran

Postal code
1937957511

Approval date
2022-04-26, 1401/02/06

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.100

Health conditions studied

1

Description of health condition studied

Burn and wound

ICD-10 code

T21.20X

ICD-10 code description

Burn of second degree of trunk, unspecified site, initial encounter

Primary outcomes

1

Description

The size of the granulation tissue formed in the wound

Timepoint

Before the intervention and six days after the last intervention

Method of measurement

Wound imaging and analysis using Image J 1.52v software (scientific image processing and analysis software)

2

Description

Wound surface and depth

Timepoint

Before the intervention and six days after the last intervention

Method of measurement

Wound imaging and analysis using Image J 1.52v software (scientific image processing and analysis software)

Secondary outcomes

1

Description

Pain from burn wound

Timepoint

Right before intervention and six days after the first intervention

Method of measurement

questions and answers from the patient

Intervention groups

1

Description

In the intervention group, collagen dressing containing condition medium soaked PVA nanofibers, loaded with curcumin/chitosan nanospheres will be applied on wounds. Based on animal studies, durability of the dressing is about 6 days but it is renewable until wound closure if it is clinically necessary. The duration of intervention will be 3 weeks. The weight ratio of nanosphere to total wound dressing is 1%.

Category

Treatment - Devices

2

Description

In control group, an available standard wound dressing based on clinician's prescription in Motahari burns hospital will be applied by following the protocols identically for all patients of group. The description of treatment and protocol will be available in details in the report of the clinical trial.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

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No 4, Maryam Alley, South Kamraniyeh Street,
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2

Recruitment center

Name of recruitment center

Shahid Motahari Educational and Medical Center

Full name of responsible person

Mostafa Dahmardehei

Street address

Shahid Motahhari Burn Hospital, Rashid-Yasemi Ave,
Valieasr Ave, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin and Stem cell Research Center of Tehran
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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin and Stem cell Research Center of 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

Jafar Ai

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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

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Full name of responsible person

Mostafa Dahmardehei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

Reza Naser

Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only information about the main outcome or the suchlike
can be shared.

When the data will become available and for how long

Access period 3 months after publication of the report

To whom data/document is available

The data can be made available to research and
academic institutions.

Under which criteria data/document could be used

The data can be used for research, industrial and
production purposes of medical equipment by observing
the intellectual rights of researchers.

From where data/document is obtainable

Rnit101@gmail.com Reza Naser

What processes are involved for a request to access data/document

For research purposes, information will be available after
a period of one week. For industrial and production
purposes, information will be available after receiving
and approving the process proposal by researchers.

Comments