Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Assessment of the efficacy of hydrogel-based wound dressing containing allantoin and silver nanoparticles in the treatment of second-degree burn wounds: A randomized clinical trial

Protocol summary

Study aim

Determining and comparing the effect of hydrogel-based wound dressing containing allantoin and silver nanoparticles on healing second-degree burns wounds

Design

Two arms parallel-group randomized trials with a control group and blinded participants on 86 patients. The blocking method is used for randomization.

Settings and conduct

This study is performed in the burn department of Imam Reza Hospital. 86 patients with second-degree burns (less than 20% of burns) are randomly assigned into two groups. Group A patients receive hydrogel-based wound dressing containing allantoin and silver nanoparticles and then dry gauze and bandaging, and group B patients receive the usual treatment (a layer of fatty gauze, dry gauze, and then bandaging). Every 48 hours, the secondary dressing is replaced, and the wound is evaluated in terms of infection and the progress of wound healing. Participants in this study are blind to the treatment they receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged between 2 to 60 years; second-degree burn wounds; diagnosed by the relevant physician; burns less than or equal to 20%; burn in upper and lower limbs and anterior trunk; wound examined by plastic and burn surgeon for necrosis and depth of the burn and the burned area is not a candidate for early surgery and the area heals without surgery and with minimal complications. Exclusion criteria: Chemotherapy; Patients taking corticosteroids; Pregnancy; Cancer, cytotoxic drugs, immunosuppressants, diabetes, and renal failure;

Intervention groups

The intervention group consisted of 43 patients who underwent hydrogel-based wound dressing containing allantoin and silver nanoparticles. The control group (43 patients) receive the usual treatment (a layer of fatty gauze, dry gauze, and then bandaging).

Main outcome variables

Duration of complete wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210918052511N2**
Registration date: **2022-04-06, 1401/01/17**
Registration timing: **prospective**

Last update: **2022-04-06, 1401/01/17**
Update count: **0**

Registration date

2022-04-06, 1401/01/17

Registrant information

Name

Omid Yazarlu

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2073

Email address

yazarlouom@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the efficacy of hydrogel-based wound dressing containing allantoin and silver nanoparticles in the treatment of second-degree burn wounds: A randomized clinical trial

Public title

Assessment of the efficacy of hydrogel-based wound dressing containing allantoin and silver nanoparticles in the treatment of second-degree burn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the ages of 2 and 60 are eligible to participate. Patients with second-degree burns diagnosed by the relevant physician Patients with burns that are less than or equal to 20% Patient with second-degree burns in upper and lower limbs and anterior trunk The wound is examined by a plastic and burn surgeon for necrosis and the depth of the burn. If the burned area is not a candidate for early surgery and can be healed without surgery and with minimal complications, the patient will be eligible to the study.

Exclusion criteria:

Delayed visit and the presence of obvious wound infection at the first visit by an infectious disease specialist Patients who are receiving chemotherapy Patients taking corticosteroids or cytotoxic medicines Pregnancy Cancer, cytotoxic drugs, immunosuppressants, and the presence of chronic diseases other than diabetes that affect wound healing, such as severe vascular disease, lupus, rheumatoid arthritis, and renal failure Smoking The presence of an underlying disease leads to a defective immune system Diabetic patients Taking drugs that lead to a defective immune system. Burns in the back of the trunk, face, head and perineum

Age

From **2 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the 86 patients would be assigned a number between 1 and 86 which is randomized by using random.org/integers in two columns. The numbers of the first column are assigned to group A and the second column is assigned to group B. With a lottery method, each column (A or B) is assigned to the intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Prior to participating in the trial, all patients or their legal representatives sign an informed consent form and are informed that they will be in one of two treatment groups. After that, participants receive the dressing based on how the allocation occurred, and they are unaware of the type of dressing received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of school of medicine-Mashhad university of medical sciences

Street address

Azadi squer- campus of Medical University of Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91379-13316

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.815

Health conditions studied

1

Description of health condition studied

Burn patients

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes

1

Description

Duration of complete wound healing

Timepoint

Every 48 hours

Method of measurement

Based on the clinical observations of an infectious disease specialist and plastic and burn surgeon

Secondary outcomes

1

Description

Wound condition (presence or absence of granulation tissue, bleeding, pain, infection, and other wound complications or healing factors).

Timepoint

Every 48 hours for 2 weeks

Method of measurement

Based on the scores of the variables and presence or absence (yes / no) and based on clinical observations of an infectious disease specialist and subspecialty of plastic surgery and burns

Intervention groups

1

Description

Intervention group: The hydrogel-based wound dressing containing allantoin and silver nanoparticles is used for two weeks and this dressing in the treatment of burn wounds accelerates wound healing, reduces the need to change dressings, shortens the duration of hospitalization, reduces scar formation, temperature control, proper air permeability to the wound and reduce pain and earlier removal of the dressing. For wound dressing, the secondary dressing (dry gauze and bandage) is changed every 48 hours and if necessary, the hydrogel dressing is also changed.

Category

Treatment - Devices

2

Description

Control group: includes the conventional treatment (a layer of fatty gauze, dry gauze and then bandaging) for two weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Burn department-Imam Reza hospital

Full name of responsible person

Dr. Omid Yazarlou

Street address

Daneshgah street-Burn department-Imam Reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91379-13316

Phone

+98 51 3802 2051

Email

Yazarlouom@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Khalil Abnous

Street address

Daneshgah Street- Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Phone

+98 51 3879 5031

Email

AbnousKh@mums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Omid Yazarlou

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work
Plastic & Reconstructive Surgery
Street address
Burn Department of Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
91379-13316
Phone
+98 51 3802 2051
Email
Yazarlouom@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Omid Yazarlou
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Plastic & Reconstructive Surgery
Street address
Burn Department of Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
91379-13316
Phone
+98 51 3802 2051
Email
Yazarlouom@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Maede Hasanpour
Position
Post-doctoral fellowship
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Azadi Square - Mashhad School of Pharmacy
City
Mashhad
Province
Razavi Khorasan
Postal code
91775-1365
Phone
+98 51 3180 1251
Email
maede.hasanpour@yahoo.com

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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data is related to the main outcome and the secondary outcome can be shared.
When the data will become available and for how long
The access period starts 3 months after the results are published
To whom data/document is available
The data is available to researchers working in academic and scientific institutions as well as people working in the industry.
Under which criteria data/document could be used
Use as a reference
From where data/document is obtainable
Dr. Maede Hasanpour - Faculty of Pharmacy - Room 233 - Phone number 09113145617- maede.hasanpour@yahoo.com
What processes are involved for a request to access data/document
After making a call via email or phone, the desired data will be sent using email or post.
Comments