Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the efficacy of using topical gel containing insulin and silver nanoparticles and topical gel containing silver nanoparticles on the duration of complete wound healing in patients with second-level burn wounds: a double-blind and randomized clinical trial

Protocol summary

Study aim
Determining and comparing the effect of topical gel containing insulin and silver nanoparticles in the treatment of second-degree burn wounds

Design
Two arms parallel-group randomized trials with a control group and double blinded on 56 patients. The blocking method is used for randomization.

Settings and conduct
This study is performed in the burn department of Imam Reza Hospital in Mashhad. 86 patients with second-degree burns (less than 20% of burns) are randomly assigned into two groups. Group A patients receive topical gel containing insulin and silver nanoparticles and then dry gauze and bandaging. Group B patients receive topical gel containing only silver nanoparticles and then dry gauze and 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, specialists, and outcome assessors 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 28 patients who receive topical gel containing insulin and silver nanoparticles The control group (28 patients) receive the topical gel containing only silver nanoparticles

Main outcome variables
Duration of complete wound healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210918052511N3**
Registration date: **2022-11-23, 1401/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-23, 1401/09/02**
Update count: **0**

Registration date
2022-11-23, 1401/09/02

Registrant information

Name
Omid Yazarlu

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-21, 1401/08/30

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of using topical gel containing insulin and silver nanoparticles and topical gel containing silver nanoparticles on the duration of complete wound healing in patients with second-level burn wounds: a double-blind and randomized clinical trial

Public title

Assessment of the efficacy of topical gel containing insulin and silver nanoparticles in the treatment of second-degree burn wounds

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

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the 56 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)

Double 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. Also, to ensure blinding, the packaging and appearance of the final gel are identical, and the packages do not design labels except for the group code. Infectious specialist and surgical and burn specialist perform all procedures on all patients. The patient, the infectious disease specialist and the subspecialist of plastic and burn surgery and the outcome assessor are blinded to the treatment groups.

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

Campus of Medical University of Mashhad, Azadi squer, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91379-13316

Approval date

2022-11-04, 1401/08/13

Ethics committee reference number

IR.MUMS.REC.1401.249

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 topical gel containing insulin 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 topical gel is also used. The prepared gel is biocompatible, and the dosage of silver nanoparticles is considered to be 80 ppm per one percent of the burn surface based on previous studies.
Category
Treatment - Drugs

2

Description
Control group: The topical gel containing only silver nanoparticles is used for two weeks. For wound dressing, the secondary dressing (dry gauze and bandage) is changed every 48 hours and if necessary, the topical gel is also used. The prepared gel is biocompatible, and the dosage of silver nanoparticles is considered to be 80 ppm per one percent of the burn surface based on previous studies.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Burn department-Imam Reza hospital
Full name of responsible person
Dr. Omid Yazarlou
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Burn department-Imam Reza hospital, Daneshgah street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Khalil Abnous
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
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Person responsible for updating data

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Dr Maede Hasanpour
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Post-doctoral fellowship
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+98 51 3180 1251
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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 251 - 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