

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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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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

Street address

Burn department-Imam Reza hospital, Daneshgah street

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Mashhad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

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

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

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

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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

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Post-doctoral fellowship

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Ph.D.

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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

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