

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the Comparison of the Antibacterial Effect of Nanosilver Spray with Silversulfadiazin Ointment on Burnt Patients

Protocol summary

Study aim

Comparison of the antibacterial effect of Silver sulfadiazine ointment and spray of silver nanoparticles on *Pseudomonas aeruginosa* and *Staphylococcus aureus* bacteria in burn wounds in patients with burn grade 2 and 3 and burn area below 20% due to heat

Design

Clinical trial with two intervention groups, with parallel, two-way blind, randomized groups

Settings and conduct

This study is being performed at Imam Reza (AS) Hospital in Birjand, South Khorasan Province. Sixty-six patients were randomly assigned to two groups of nanosilver sprays or sulfur sulfadiazine ointment. Then, the presence of infection in 3 and 6 days after hospitalization and the size of the burn wound on 0 and 7 days after hospitalization will be examined.

Participants/Inclusion and exclusion criteria

The study population of patients admitted to the burn ward of Imam Reza (AS) Hospital in Birjand with burn grade 2 and 3 and burn area below 20% will be in 1399. Criteria for entering the study include: having conscious consent of the patient or his close companion to enter the study, at least 12 mg / dl hemoglobin, degree of burns 2 and 3 and percentage of thermal burns below 20%, no intervention to wash and burn the burn before visiting The hospital and the ability to answer questions should be the patient himself or his companion. And the criteria for leaving the study include: patients taking corticosteroids for more than a month, suppressing the immune system and chemotherapy, not having diabetes, AIDS, hypertension, skin allergies, dissatisfaction to continue studying.

Intervention groups

Burnt patients who will be treated with nanosilver spray or Silver Sulfadiazine ointment when dressing.

Main outcome variables

Wound size Wound site infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N4**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-19, 1399/03/30**

Update count: **0**

Registration date

2020-06-19, 1399/03/30

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-19, 1399/03/30

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Comparison of the Antibacterial Effect of Nanosilver Spray with Silversulfadiazin Ointment on Burnt Patients		City Birjand Province South Khorasan Postal code 9717811674
Public title	Comparison of nanosilver spray with silorsulfadiazine ointment in burns	Approval date 2020-06-10, 1399/03/21
Purpose	Treatment	Ethics committee reference number IR.BUMS.REC.1399.089
Inclusion/Exclusion criteria	Inclusion criteria: Having conscious consent of the patient or his close companion to enter the study Minimum hemoglobin mg / dl 12 Grade 2 and 3 burns Percentage of thermal burns below 20% Failure to perform surgery to wash and burn the burn before visiting the hospital Ability to answer questions Exclusion criteria:	Health conditions studied
Age	No age limit	1
Gender	Both	Description of health condition studied Burning
Phase	3	ICD-10 code M61.3
Groups that have been masked	- Participant - Outcome assessor	ICD-10 code description Calcification and ossification of muscles associated with burns
Sample size	Target sample size: 66 More than 1 sample in each individual Number of samples in each individual: 2 If there is fuel in two different locations, sampling will be performed from two different locations.	Primary outcomes
Randomization (investigator's opinion)	Randomized	1
Randomization description	Blocking method of Simple random sampling	Description Wound size
Blinding (investigator's opinion)	Double blinded	Timepoint Zero day (hospitalization) and day 7 after hospitalization
Blinding description	Study participants Consequence Assessor	Method of measurement The size of the patient's wound will be measured based on the Betsy Jensen checklist
Placebo	Not used	Secondary outcomes
Assignment	Parallel	1
Other design features		Description Wound infection
Secondary Ids	empty	Timepoint 3 and 6 days after hospitalization
Ethics committees		Method of measurement Sampling of the wound by a sterile swab using the Levine technique
1		Intervention groups
Ethics committee		1
Name of ethics committee	Ethics Committee of Birjand University of Medical Sciences	Description Intervention group: Use a nanosilver spray when replacing a burn wound dressing (spray on the wound site to wet the entire burn wound).
Street address	Ghaffari Str	Category Treatment - Drugs
		2
		Description

Intervention group: Use of Silver Sulfadiazine ointment when replacing burn wound dressings (the burn site will be covered with a topical ointment of Silver Sulfadiazine 1.5 mm thick that is routinely used to treat burn wounds).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital-Birjand

Full name of responsible person

Dr. AbdolVahhab Javaheri

Street address

Moallem BLV

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand 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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaghegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available