Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of probiotic Lactobacillus plantarum with common treatment in the preventive of infection and wound healing

Protocol summary

Study aim
Effect of probiotic ointment on prevention and control of infection, wound healing and shortening wound healing time

Design
Clinical trial with control group, with parallel groups, Non-random assignment to intervention and control groups was not blinded

Settings and conduct
Twenty patients from Motahhari burn hospital in Tehran were divided into two groups (control group) and experimental group. (Recipient of probiotic product) will be selected. The control group will receive Silver Sulfadiazine ointment and the experimental group will receive Lactobacillus plantarum ointment for one week.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients with grade II superficial burn wounds without other secondary diseases Exclusion criteria: Patients with deep grade II burns, grade III and IV, as well as patients with superficial grade II burns who have concomitant kidney disease, hypertension, or secondary infection.

Intervention groups
Intervention group: Includes patients with grade II burn wounds who receive treatment with probiotic product. Intervention group (control): Includes patients with grade II burn wounds who receive routine antibiotic treatment.

Main outcome variables
Burn wound healing Prevention of burn infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191011045055N1**
Registration date: **2019-11-13, 1398/08/22**
Registration timing: **prospective**
Last update: **2019-11-13, 1398/08/22**
Update count: **0**

Registration date
2019-11-13, 1398/08/22

Registrant information

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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
2019-12-21, 1398/09/30

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of probiotic Lactobacillus plantarum with common treatment in the preventive of infection and wound healing

Public title
the survey of effect of probiotic on wound healing in burn patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
(deep second-degree) burn and (Superficial three-degree) burn with a percentage below 20% and no primary infection
Exclusion criteria:
Age of under 10 and over 65 due to weak immune system Diabetes, hypertension, kidney and seizures disease Use of antibiotics during treatment Other infections (except burns)

Age
From **10 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
the side of right and left of body

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Anti-Microbial Resistance Research center, Institute of Immunology and Infectious Diseases, Rasole hospital, Niayesh st, Sattarkhan St

City
Tehran

Province
Tehran

Postal code
123

Approval date
2018-10-28, 1397/08/06

Ethics committee reference number
IR.IUMS.REC.1397.614

Health conditions studied

1

Description of health condition studied
Infection and scar of burn wound

ICD-10 code
M61.30

ICD-10 code description
Calcification and ossification of muscles associated with burns, unspecified site

Primary outcomes

1

Description
Percentage of people with burn wound healing

Timepoint
The study will start (at the time of topical treatment) and the duration of treatment will be 7 days.

Method of measurement
Wound culture-Morphological observation of wounds

Secondary outcomes

1

Description
Prevention of infection after discharge from hospital

Timepoint
Two weeks after discharge

Method of measurement
diagnosis of Infectious disease specialist

Intervention groups

1

Description
Control group:Routine treatment group with antibiotics

Category
Treatment - Drugs

2

Description
Intervention group: Group receiving the probiotic product

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahari Hospital

Full name of responsible person
dr Mehnoosh Momeni

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Motahari Hospital, Rashid Yasemi St, Vanak
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1

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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
Iran 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

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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
Yes - There is 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
Title and more details about the data/document
Drug efficacy report after completion of the treatment process will be presented
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
Academic and industrial people
Under which criteria data/document could be used
Provided for use in the article with citing the source
From where data/document is obtainable
021-64352397
What processes are involved for a request to access data/document
After the clinical phase is completed, statistical analysis will be performed on the data and some of it will be shared after verification and .
Comments