Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

The effect of Lactocare probiotics on the treatment of acute and severe thermal burns

Protocol summary

Study aim
Evaluation of the effect of adding lactocare probiotic products in the treatment of acute and severe thermal burns

Design
A parallel triple-blind clinical trial on 40 patients with intervention and control group. The selection of samples will be done based on the list of version 9 of SAS software and the researcher has no information about the selection sequence of samples and the type of medication used and this is done by the nursing office.

Settings and conduct
Location: Velayat Hospital(Rasht).The patient, researcher, and evaluator are blinded and samples are randomly selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are 15-89 years, within 24 hours after the occurrence of second or third degree burns with TBSA between 20-70%, people with thermal burns that are not associated with other trauma and the ability to feed by the digestive system.Exclusion criteria: Patients under 15 and over 89, first-degree burns, TBSA under 20 and over 70%, chemical and electrical burns, patients who are unable to feed by the digestive system, patients with gastrointestinal, immunodeficiency, chronic diseases such as diabetes and sepsis during hospitalization, pregnancy and breastfeeding.

Intervention groups
A (probiotic group) B (placebo group) Then each of groups A and B will be divided into two subgroups based on TBSA: 1) 20 to 40% 2) 41 to 70%

Main outcome variables
Proportion of duration of hospitalization and duration of wound healing to TBSA, mortality,number of skin graft surgeries, Graft Loss, gasteric complications, infection, use of antibiotics, antifungal drug, serum CRP level, serum IgA level, blood lymphocyte, neutrophil count and serum albumin level.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210524051384N3**
Registration date: **2021-10-15, 1400/07/23**
Registration timing: **prospective**

Last update: **2021-10-15, 1400/07/23**
Update count: **0**

Registration date
2021-10-15, 1400/07/23

Registrant information
Name
mohammadreza mobayen
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3336 8540
Email address
maziar.mobayen@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-11-22, 1401/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of Lactocare probiotics on the treatment of acute and severe thermal burns

Public title
Evaluation of the effect of Lactocare in the treatment of burns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 15-89 years aged, within 24 hours after the occurrence of second or third degree burns with TBSA (Total Body Surface Area) between 20-70%, People with thermal burns are not accompanied by other trauma and have the ability to feed by the digestive system
Exclusion criteria:
Patients with digestive diseases Immunodeficiency diseases Chronic diseases such as diabetes and sepsis during hospitalization pregnancy and breastfeeding
Age
From **15 years** old to **89 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used to generate a random allocation sequence is based on the list of version 9 of SAS software. In order to randomize the treatment between groups, permutation randomization block method with size 4 and considering TBSA classes between 20-40 and 41-70 will be performed. Considering the time of entry of patients into the study and the label of the drug (A and B, considering that the study is triple blind study, only one of the analysts who is not involved in the study process is aware of the type of treatment assigned). This list is in a sealed envelope in the nursing desk of the maintenance department, and after the study begins, the envelope will be opened and random blocks will be taken out of the envelope separately for the day, and patients will be treated accordingly.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to blind the studied samples (patients), placebo, which is completely similar to the probiotic products in terms of shape and inactive compounds, will be given to the patients in the control group. In order to blind the researcher (the treating physician who monitors the treatment process of patients in terms of studied variables such as length of hospital stay, etc.). The selection of samples will be done based on the list of version 9 of SAS software and the researcher has no information about the sequence,the selection of samples and the type of medicine is not consumed and it will be done by the nursing office.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committees of Guilan University of Medical science
Street address
Guilan University of Medical science
City
Rsht
Province
Guilan
Postal code
4144666949
Approval date
2021-09-29, 1400/07/07
Ethics committee reference number
IR.GUMS.REC.1400.303

Health conditions studied

1

Description of health condition studied
Burns
ICD-10 code
T29.2-T29.
ICD-10 code description
Burns of multiple regions, at least one burn of third degree mentioned, Burns of multiple regions, no more than second-degree burns mentioned

Primary outcomes

1

Description
Total Body Surface Area
Timepoint
Percentage of burns
Method of measurement
Measurements based on Wallace criteria

2

Description
Proportion of length of hospital stay to TBSA

Timepoint
Lenght of hospitalization based on patient records and follow-up until the day of discharge to TBSA
Method of measurement
Number

3

Description
Mortality
Timepoint
Death means the absence of vital signs during the patient's hospitalization
Method of measurement
Dead / Alive

4

Description
Number of days of antibiotic usage
Timepoint
Lenght of hospitalization based on patient records and follow-up until the day of discharge
Method of measurement
Based on day

5

Description
Number of days of taking antifungal medicine
Timepoint
Based on the patient's record and follow-up until the day of discharge
Method of measurement
Based on day

6

Description
Number of days of gastric complications (diarrhea, constipation, vomiting, laxative used)
Timepoint
Based on the patient's history and check-up and follow-up until the day of discharge
Method of measurement
Based on day

7

Description
Study group
Timepoint
Based on random assignment to study groups
Method of measurement
Intervention / Control

Secondary outcomes

1

Description
Graft loss
Timepoint
Graft loss that is diagnosed under the supervision of a surgeon and due to symptoms such as swelling, redness, infection, etc.
Method of measurement
Yes / no

2

Description
WLOS / TBSA (wound healing duration ratio to TBSA)
Timepoint
Based on the expert's observations about the location of the skin wound
Method of measurement
Number

3

Description
Number of days of infection
Timepoint
Based on evidence and results of blood or urine culture or wound or sputum
Method of measurement
Day

4

Description
CRP serum levels
Timepoint
Based on laboratory results. Day of hospitalization and the fourth, seventh, fourteenth days of hospitalization.
Method of measurement
mg/L

5

Description
IgA serum levels
Timepoint
Based on laboratory results. Day of hospitalization and the fourth, seventh, fourteenth days of hospitalization.
Method of measurement
mg/dL

6

Description
Blood lymphocyte and neutrophil count
Timepoint
Based on laboratory results. Day of hospitalization and the fourth, seventh, fourteenth days of hospitalization.
Method of measurement
cells/mm^3

7

Description
Albumin serum levels
Timepoint
Based on laboratory results. Day of hospitalization and the fourth, seventh, fourteenth days of hospitalization.

Method of measurement

gr/dL

Intervention groups

1

Description

Intervention group: The probiotic product is two Lactocare capsules daily for intervention group (A). Two oral capsules will be started daily for ten days after the burn and continue until 95% of the burn wound heals. During the treatment process, a nasogastric tube is inserted to feed the patient. The probiotic products will be first dissolved in an appropriate amount of distilled water and then the solution obtained will been given to the patient by the nasogastric tube. For any reason, the patient's feeding method changes to injectable form, the patient will be excluded from the study if we are unable to provide intestinal nutrition to the patient for more than 48 hours. Lactocare probiotic products will be added to the routine treatment of burns for patients in the intervention group and none of the patients included in the study (both intervention group and control group) will be not banned of routine treatment of burn patients. For all patients, the amount of TBSA per day of hospitalization will calculate by using the Wallace scale. In this study, constipation is defined as non-defecation for three consecutive days and diarrhea as soft defecation more than four times a day or defecation of two or more watery stools in 24 hours. Diarrhea that occurs after taking a laxative will not be included in this count. The presence of infection is assessed using clinical evidence (discharge, new erythema, wound odor, unexplained fever, anorexia, or urinary or respiratory symptoms) followed by relevant blood, urine, wound, or sputum tests.The duration of hospitalization is defined as the length of time spent from the day of hospitalization to the day of discharge and is compared by the percentage of burns between groups A and B. Also, the calculation of the duration of burn wound healing is the time elapsed until 95% of the burn surface heals, which is usually 10 days after the last skin graft, and this variable is also compared in terms of the percentage of burns between the two groups. In case of skin graft for patients, the course of changes will be examined under the supervision of a surgeon, and in case of symptoms related to graft loss, the relevant information is recorded in the draft. Laboratory studies including CRP, albumin serum level, IgA immunoglobulin level and blood lymphocyte and neutrophil count are measured through venous blood samples according to the laboratory protocol of Velayat Hospital on the day of hospitalization and on the fourth, seventh and fourteenth days of hospitalization. The contract obtained with the bio-fermentation company (the manufacturer of the probiotic product Lactocare) regarding the cost of providing the same medicine and placebo, the necessary cooperation will be done, and the mentioned contract was entered in the appendices section of the site.

Category

Treatment - Drugs

2

Description

Control group: Placebo product for control group (B) Two oral capsules will be started daily for ten days after the burn and continue until 95% of the burn wound heals. During the treatment process, a nasogastric tube is inserted to feed the patient. The probiotic products will be first dissolved in an appropriate amount of distilled water and then the solution obtained will been given to the patient by the nasogastric tube. For any reason, the patient's feeding method changes to injectable form, the patient will be excluded from the study if we are unable to provide intestinal nutrition to the patient for more than 48 hours. Lactocare probiotic products will be added to the routine treatment of burns for patients in the intervention group and none of the patients included in the study (both intervention group and control group) will be not banned of routine treatment of burn patients. For all patients, the amount of TBSA per day of hospitalization will calculate by using the Wallace scale. In this study, constipation is defined as non-defecation for three consecutive days and diarrhea as soft defecation more than four times a day or defecation of two or more watery stools in 24 hours. Diarrhea that occurs after taking a laxative will not be included in this count. The presence of infection is assessed using clinical evidence (discharge, new erythema, wound odor, unexplained fever, anorexia, or urinary or respiratory symptoms) followed by relevant blood, urine, wound, or sputum tests.The duration of hospitalization is defined as the length of time spent from the day of hospitalization to the day of discharge and is compared by the percentage of burns between groups A and B. Also, the calculation of the duration of burn wound healing is the time elapsed until 95% of the burn surface heals, which is usually 10 days after the last skin graft, and this variable is also compared in terms of the percentage of burns between the two groups. In case of skin graft for patients, the course of changes will be examined under the supervision of a surgeon, and in case of symptoms related to graft loss, the relevant information is recorded in the draft. Laboratory studies including CRP, albumin serum level, IgA immunoglobulin level and blood lymphocyte and neutrophil count are measured through venous blood samples according to the laboratory protocol of Velayat Hospital on the day of hospitalization and on the fourth, seventh and fourteenth days of hospitalization. The contract obtained with the bio-fermentation company (the manufacturer of the probiotic product Lactocare) regarding the cost of providing the same medicine and placebo, the necessary cooperation will be done, and the mentioned contract was entered in the appendices section of the site.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital
Full name of responsible person
Dr.Mohammadreza Mobayen
Street address
Namjoo street
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
maziar.mobayen@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr.Mohammadreza Naghipour
Street address
Deputy of Research and Technology,in front of 17 Shahrivar Hospital, Namjoo St,
City
Rasht
Province
Guilan
Postal code
4193713191
Phone
+98 13 3333 6394
Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Dr.Mohammadreza Mobayen
Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Namjoo St
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
maziar.mobayen@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr.Mohammadreza Mobayen
Position
Director of the Department of Surgery, Head of the Burn and Plastic Surgery Hospital, Head of the Bu
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Namjo St,
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
maziar.mobayen@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Sepideh Pirdastan
Position
PHD
Latest degree
Medical doctor
Other areas of specialty/work

General Practitioner

Street address
Namjo st,.

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3336 8540

Email
sepidehpirdastan@gmail.com

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