

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)

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+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		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.	
Public title	Evaluation of the effect of Lactocare in the treatment of burns	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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	Other design features	
Age	From 15 years old to 89 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	N/A	1	
Groups that have been masked	- Participant - Care provider - Investigator	Ethics committee	
Sample size	Target sample size: 80	Name of ethics committee	Research Ethic Committees of Guilan University of Medical science
Randomization (investigator's opinion)	Randomized	Street address	Guilan University of Medical science
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.	City	Rsht
Blinding (investigator's opinion)	Triple blinded	Province	Guilan
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	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

Length 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

Length 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/mm³

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 be 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 be 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

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City

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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
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sepideh Pirdastan

Position

PHD

Latest degree

Medical doctor

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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