Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of probiotics in the therapy of Pediatrics thermal Burn: A prospective double- blind, controlled clinical trial

Protocol summary

Study aim
The effect of probiotic on therapy of thermal burn in children
Design
A prospective , with controlled parallel group, randomized , double- blind clinical trial, phase 2 of 100 patients. For randomization we used rand function of Excel software
Settings and conduct
This is a prospective , randomized , double- blind clinical trial in which patients and investigator are bind to content of packages. By random allocation , the patients will divide to two group (n=50)
Participants/Inclusion and exclusion criteria
Inclusion criteria - Children between 1-15 years old - Total body surface of burn 10-50% - Deep area of burn 5-10% Exclusion criteria - Children with history of chronic GI diseases - Children with history of chronic diseases for example diabetes - Children with upper respiratory tract burn and inhalation injury - Children with known hereditary and immunodeficiency - Children with electrical and chemical burn
Intervention groups
Case group will take probiotic Control group will take placebo
Main outcome variables
The main outcomes of this study including decrease in infection rate; the length of hospital stay; the need to skin graft and mortality in children with thermal burn

General information

Reason for update
Acronym
پروبیوتیک در سوختگی
IRCT registration information
IRCT registration number: **IRCT20210708051822N1**
Registration date: **2021-08-02, 1400/05/11**
Registration timing: **prospective**
Last update: **2021-08-02, 1400/05/11**
Update count: **0**
Registration date
2021-08-02, 1400/05/11

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-23, 1400/06/01
Expected recruitment end date
2021-11-22, 1400/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of probiotics in the therapy of Pediatrics thermal Burn: A prospective double- blind, controlled clinical trial

Public title
Effect of probiotics in the therapy of Pediatrics Burn
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children between 1-15 years old Burn with total body

surface area 10-50% Burn with deep area between 5-10%

Exclusion criteria:

Children with chronic GI diseases Children with chronic diseases for example diabetes Children with upper respiratory tract or inhalation injury Children with hereditary and congenital immune system disorders children with chemical and electrical burn

Age

From **1 year** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After hospitalization, patients will be divided in two group of case (probiotic) and control(placebo) by simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The packages of probiotic and placebo will be designed in the same form. Only principle investigator knows the content of packages . Patient and investigator or clinician are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences

Street address

Ethics Committees of Iran University of Medical Sciences, Central building of Iran University of Medical Sciences, next to Milad tower, Hemmat highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.IUMS.REC.1400.277

Health conditions studied

1

Description of health condition studied

Thermal Burn in children

ICD-10 code

T20-T32

ICD-10 code description

Burn and corrosion

Primary outcomes

1

Description

The rate of infection in thermal burn of children

Timepoint

Zero (admission day), 4, 7 and 14 day and until one year after hospitalization

Method of measurement

To calculate the number of positive culture reported by laboratory in thermal burn of children according to patients file.

2

Description

The length of hospital stay in thermal burn of children

Timepoint

Time of discharge or death

Method of measurement

To calculate the length of hospital stay on the time of discharge or death according to patients file.

3

Description

The need to skin graft in thermal burn of children

Timepoint

From discharge until one year

Method of measurement

To calculate the number of skin graft from discharge until one year according to patients file.

4

Description

Mortality due to thermal burn of children

Timepoint

From hospitalization until one year

Method of measurement

The mortality rate (the proportion of death to number of hospitalized patients) in thermal burn of children

Secondary outcomes

1

Description
Length of hospital stay
Timepoint
Date of discharge and one year after burn
Method of measurement
Number of hospitalized days

2

Description
The need to skin graft
Timepoint
From discharge until one year after burn
Method of measurement
The number of skin grafts

Intervention groups

1

Description
Intervention group: Probiotic supply group that will receive oral package including 1- lactobacillus rhamnosus 2- lactobacillus rotteri 3- lactobacillus acidophilus 4-lactobacillusbulgaricus 5- lactobacillus casei 6-Bifidobacterium infantis 7-Bifidobacterium breve 8-Bifidobacterium bifidum 9-Bifidobacterium lactis 10-Streptococcus thermophilus with density of CFU 109 plus prebiotic of Fructooligosaccharides. This package is Gluten free and produced by Farabiotic Company . This oral powder will be used twice daily for 14 days by 50 cases of control group.
Category
Treatment - Other

2

Description
Control group: They will receive a package of placebo including food material and in the same form of probiotic package. The oral placebo is produced by Farabiotic company and will be used by 50 cases of control group twice daily for 14 days.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Burn Hospital
Full name of responsible person
Hossein Masoumi Asl
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Masoumi Asl

Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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