

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 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

Name

Hossein Masoumi-Asl

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Street address

Shahid Motahari Burn Hospital Yasami Ave, Valiasr St, Tehran

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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

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Iran University of Medical Sciences

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Position

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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