Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of Synbiotic Supplementation on Inflammatory Indices in Children with Sepsis Hospitalized in the Intensive Care Unit in comparison with placebo

Protocol summary

Study aim

Investigating the effect of synbiotic supplementation on inflammatory indices in children with sepsis hospitalized in the intensive care unit

Design

A clinical trial with a control group, parallel-group, triple-blind, randomized, phase 1 study on 54 patients. Sealedenvelope site was used for randomization

Settings and conduct

Patients aged 1 month to 10 years with sepsis hospitalized or admitted to the pediatric intensive care unit of Akbar Mashhad Hospital. The intervention group will receive Kid Locket synbiotic product with a daily dose of 2 sachets and the control group will receive 2 placebo sachets for 7 days. The concentration of inflammatory factors (ESR, CRP, TNF α, IL6) on the seventh day and the duration of hospitalization, the mortality rate, the duration of ventilator connection and the need for antibiotic treatment will be compared in the two groups.

Participants/Inclusion and exclusion criteria

inclusion criteria : any patient admitted to the pediatric intensive care unit with a diagnosis of sepsis with the possibility of hospitalization for more than 4 days in the PICU, patients in the age group of 1 month to 10 years, parental consent to participate in the project. Conditions of non-entry: immunodeficiency or malignancy, people who are on steroid therapy or immunotherapy,Congenital malformations incompatible with life, previous gastrointestinal surgery in the last month, ulcerative colitis, short bowel syndrome.

Intervention groups

The intervention group will receive Kidilact Synbiotic product containing 10 bacterial strains (produced by zisttakhmir Company) with a daily dose of 2 sachets and the control group will receive 2 placebo sachets (produced by zisttakhmir Company) for 7 days.

Main outcome variables

Interleukin 6 ؛C-reactive protein ؛Erythrocyte sedimentation rate؛ Tumor necrosis factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230523058266N1**
Registration date: **2023-10-30, 1402/08/08**
Registration timing: **prospective**

Last update: **2023-10-30, 1402/08/08**
Update count: **0**

Registration date

2023-10-30, 1402/08/08

Registrant information

Name
Ali Chamani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4333 4400

Email address
chamania4012@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Synbiotic Supplementation on Inflammatory Indices in Children with Sepsis Hospitalized in the Intensive Care Unit in comparison with placebo

Public title

Investigating the Effect of Synbiotics on Inflammatory Indicators

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Any Patient admitted to the Pediatric Intensive Care Unit with a Diagnosis of Sepsis and Possibility of Hospitalization for more than 4 Days in the PICU children aged 1 month to 10 years consent of parent to participation of their children to study

Exclusion criteria:

Immunodeficiency or Malignancy steroid Therapy or Immunotherapy Congenital Abnormalities Incompatible with life Previous Gastrointestinal Surgery in the last month Ulcerative Colitis Short Bowel Syndrome

Age

From **1 month** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking using blocks of 4 and 6 Using the site sealedenvelope Synbiotics or placebos are packaged as a solution that looks, smells, and tastes the same in containers that look the same. The synbiotic or placebo is packaged in opaque packages with a random allocation number on it. Allocation of random number and preparation of packages containing synbiotic or placebo will be done by a person not involved in patient registration, data collection, data entry and analysis

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant blinding: Due to the administration of a placebo with the same shape, taste and smell as the synbiotic supplement, the patient will be blinded to the treatment itself. Data analyzer: due to the use of the site and random block to allocate the intervention or placebo, the data analyzer will be blinded to the intervention. Researcher, clinical outcome assessor and clinical caregiver: due to the use of the site and random block for allocating intervention or placebo, the data analyzer will be blinded to the intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi square, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2023-09-19, 1402/06/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.352

Health conditions studied

1

Description of health condition studied

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified organism

Primary outcomes

1

Description

Interleukin-6

Timepoint

The beginning of the study (before the start of the intervention) and the 7th day after the start of taking the synbiotic supplement

Method of measurement

Interleukin 6 ELISA kit

Secondary outcomes

1

Description
C reactive protien
Timepoint
The beginning of the study (before the start of the intervention), 7 days after the start of taking the synbiotic supplement.
Method of measurement
Measurement of serum levels

2

Description
Tumor necrosis factor
Timepoint
The beginning of the study (before the start of the intervention), 7 days after the start of taking the synbiotic supplement.
Method of measurement
Measurement of serum levels

3

Description
Erythrocyte sedimentation rate
Timepoint
The beginning of the study (before the start of the intervention), 7 days after the start of taking the synbiotic supplement.
Method of measurement
Measurement of serum levels

Intervention groups

1

Description
Intervention group:Kidilact synbiotic supplement containing 10 strains of bacteria produced by zisttakhmir company with a dose of 2 sachets daily for 7 days
Category
Treatment - Drugs

2

Description
Control group: Control group: Placebo from zisttakhmir 2 sachets daily for 7 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Hospital
Full name of responsible person
Fatemeh Roudi
Street address
In front of Shahid Kaveh 14,Shahid Kaveh Blvd,Taleghani town
City
Mashhad
Province
Razavi Khorasan
Postal code
9177897157
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ak.pr@mums.ac.ir
Web page address
https://akbar.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice President of Research and Technology, Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayor Mobarhan
Street address
East door of university campus, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
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vcresraech@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice President of Research and Technology, Mashhad 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

Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Roudi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Fax
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chamaniA4012@mums.ac.ir

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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The data related to the demographic information of the people, the information of the biochemical tests of the people and the information related to the supplement used in the study will be at the disposal of Mashhad University of Medical Sciences as the organization under its supervision and in the comprehensive database of the University of Sciences. Mashhad Medical Center will be located.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
The information will be available to the researchers and the industry upon the discretion and approval of all project partners.
Under which criteria data/document could be used
The information will be available to the researchers and the industry upon the discretion and approval of all project partners.
From where data/document is obtainable
To receive information, the email of the responsible author and the first author will be provided to people in the journal in which the project will be published, and with an explanation of the reason for the need to access the desired study, if approved and at the discretion of the project partners, access to the data , will be given. Corresponding author: Dr. Fatemeh Roudi Email address: RoudiF@mums.ac.ir Phone: 05131891509 First author: Ali Chamani Email address: chamaniA4012@mums.ac.ir

Phone: 09021530646

What processes are involved for a request to access data/document

By requesting by e-mail to the responsible author or the first author and explaining the reason for the need to access the desired study, the data access plan will be given upon approval and discretion of the colleagues.

Comments