Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the effect of preventive symbiotic administration on the incidence of allergic diseases in children aged 0 to 5 years, a clinical trial study

Protocol summary

Study aim
Investigating the effect of preventive symbiotic prescription on the incidence of allergic diseases in children 0 to 5 years old

Design
The clinical trial has a placebo group, in parallel, double-blind, randomized, in phase 2 of the study, 400 patients selected from the first phase will be conducted. Random sequence generation software will be used for randomization.

Settings and conduct
This study will be conducted in the health centers of Mashhad University of Medical Sciences. This study is double-blind. The symbiotic and placebo drops are similar in appearance, taste and smell. The symbiotic and placebo drops, which are completely similar, have been placed in sterile packages and unique codes have been assigned to each package. The patient is the delivery person. The medicine given to the patient and the filling of the questionnaires are of the type of medicine inside the package, blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Completing the consent form to participate in the research 2. 38 to 42 weeks term baby with a normal weight of 2500 to 3999 grams at the time of birth 3. Based on the questionnaire Module 2.5: Risk factor questionnaire, the family is at risk for allergic diseases 4. Residents of Mashhad 5. No history of immune deficiency in the family

Intervention groups
The prescription of symbiotic drops will be given in the form of one cc per day, every other month for12 months. Placebo group: Placebo drops will be given in the form of one cc per day for a period of 12 months. There is no control group in this study

Main outcome variables
Incidence of jaundice; infantile-colic; atopic-dermatitis; allergic rhinitis; eczema; asthma; upper respiratory infection; pneumonia and diarrhea

General information

Reason for update

Acronym
MSS (Mashhad symbiotic study)

IRCT registration information
IRCT registration number: **IRCT20211211053351N2**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date
2023-11-25, 1402/09/04

Registrant information

Name
sadeghi tahereh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2028-12-21, 1407/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of preventive symbiotic administration on the incidence of allergic diseases in children aged 0 to 5 years, a clinical trial study

Public title
Preventive symbiotic administration on the incidence of allergic diseases in children aged 0 to 5 years
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Be a resident of Mashhad city Completing the consent form to participate in the research Term neonatal 38 to 42 weeks Normal weight at birth is 2500 to 3999 grams According to Module 2.5: Risk factor questionnaire, the family is at risk for allergic diseases
Exclusion criteria:
Abnormalities of the newborn in the cardiac, skeletal, nervous system
Age
From **1 day** old to **5 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **400**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization methods are used and The randomization program is repeated until the desired balance is achieved. The sample size is 200 people in each group, in the event that after the completion of the simple randomization program, if the inequality between the groups is more than 20 people, the creation of a random sequence will be repeated and the new program will replace the previous program. Researchers will repeat this process until receive the desired criterion. The number of samples allocated to each of the studied groups will be equal. The size of all blocks is equal and we will have two groups of 6 blocks in this trial (including 3 participants in the intervention group and 3 participants in the control group). The randomization tool is also used from the software for generating random sequences (random allocation software), which in addition to simple randomization, these random sequence generating software are capable of generating random sequences using the block method.
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting the samples, none of the participants will be aware of randomization and allocation to groups. Physicians will be given a table of pre-coded numbered numbers and patients will be entered into the study in order of table numbers. Therefore, the present study will be double-blind. Symbiotic drops and placebo drops manufactured by Zisttakhmir will be given to the control and intervention groups. And the placebo is the same in terms of shape, color and size and is delivered to the patient's parents in the package.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mashhad University of Medical Sciences
Street address
Knowledge and Health City, In the end of Shahid Fakouri Blvd (In front of Fakouri ۹۴), Mashhad - Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9919191778
Approval date
2023-09-09, 1402/06/18
Ethics committee reference number
IR.MUMS.REC.1402.217

Health conditions studied

1

Description of health condition studied
Allergic diseases in children
ICD-10 code
J45.0
ICD-10 code description
Predominantly allergic asthma

Primary outcomes

1

Description
Incidence of jaundice
Timepoint

The first month

Method of measurement

The bilirubin of newborns will be recorded up to 2 weeks and the management of jaundice, which includes hospitalization, use of medicine, blood exchange and its treatment measures, will be evaluated.

2

Description

Incidence of infantile colic

Timepoint

First month, third month of birth

Method of measurement

According to Wessel's diagnostic criterion, crying of a healthy infant for 3 hours a day, for 3 days a week and in 3 consecutive weeks is infantile colic, which is measured by the infantile colic scale questionnaire (ICS). This scale includes 22 items or questions that were scored from very little (with a score of 1) to very high (with a score of 5).

3

Description

Atopic dermatitis

Timepoint

The effect of Symbiotic use on the occurrence of allergic diseases in children will be evaluated at one month, 3 months, 12 months, 24 months, and 60 months.

Method of measurement

The severity of the disease will be determined based on the SCORAD criteria, and this questionnaire will be completed by the interviewer and with the cooperation of the parents of infants or their caregivers.

4

Description

Allergic rhinitis

Timepoint

Third month, 12 months, 24 months, 60 months

Method of measurement

Diagnosis of allergic rhinitis based on history of rhinorrhea, nasal congestion and sneezing, itching, (if two or more of these symptoms are present for at least one hour on most days), along with at least one atopy criterion (family history of allergies, Elevated IgE or positive skin test is present Nose and throat examination will be used to rule out infectious rhinitis.

5

Description

Asthma

Timepoint

Third month, 12 months, 24 months, 60 months

Method of measurement

The severity of asthma and the frequency of asthma will be evaluated based on the ISAAC questionnaire

6

Description

Respiratory Acute Infections

Timepoint

Third month,12 months, 24 months, 60 months

Method of measurement

Acute respiratory infections from a wide range of diseases such as throat infections, colds, and tonsillitis, flu, and lower respiratory tract diseases will be separated with the final diagnosis of pneumonia and bronchiolitis.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After completing the research consent form, one symbiotic drop will be given to the family every month. Necessary training on how to store and use drops will be given. The dosage will be given as one cc per day for a period of 12 months.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers under Mashhad University of Medical Sciences

Full name of responsible person

Hamid Ahanchian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number
4011745

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Zisttakhmir Co

Proportion provided by this source
10

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
Hamid Ahanchian
Position
Associate professor
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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable