

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of probiotic nasal spray efficacy in prevention of COVID-19 and other common respiratory viruses in asthmatics children

Protocol summary

Study aim

Investigation of preventing effect of probiotic nasal spray in COVID-19 and other common respiratory viruses

Design

Randomized, superiority, parallel group trial with blinded outcome assessment. 90 participants; phase 3; simple randomization- triple blinded

Settings and conduct

Allergy clinic of Akbar children's hospital, Mashhad University of Medical Sciences university. Participants are children aged 6-18 years old with asthma diagnosis according GINA 2020 and confirmed by allergist. They will receive nasal spray for one month and they will asked about any sign or symptoms of viral infection during last year, and those with negative history will recruited. after production of nasal spray, pharmacist will use rand function of Excel app and randomized sprays, then numbered nasal sprays will use blindly. It will administered in first month of autumn, so virus exposure will be almost similar in school aged children. In next month they will asked about these parameters(with 2 weeks interval): fever; new onset respiratory symptoms or exacerbation of preexisting symptoms; gastrointestinal presentations; taste or olfactory disorders.

Participants/Inclusion and exclusion criteria

Persistent asthma children aged between 6-18 years old; without history of COVID-19 infection, or any contraindications for probiotic

Intervention groups

Patients will receive one month, probiotic nasal spray- one puff in each nostril, two time per day- containing lactobacillus reuteri and lactobacillus casei

Main outcome variables

Fever; cough; dyspnea; diarrhea; vomiting; abdominal pain; taste or olfactory disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200117046164N2**

Registration date: **2021-09-24, 1400/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-24, 1400/07/02**

Update count: **0**

Registration date

2021-09-24, 1400/07/02

Registrant information

Name

Nasrin Moazzen

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3840 0000

Email address

moazzenn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of probiotic nasal spray efficacy in prevention of COVID-19 and other common respiratory viruses in asthmatics children

Public title
Probiotic nasal spray in prevention of COVID-19 and other common respiratory viruses

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Asthmatic children
Exclusion criteria:
Positive history of COVID-19 Autoimmunity Malignancy
Complication after nasal spray use Unwilling to continue participation in trial

Age
From **6 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: simple randomization; unit of randomization: individual; allocation concealment: closed envelope

Blinding (investigator's opinion)
Triple blinded

Blinding description
After preparation of nasal sprays, each of them will have a randomized code; then clinicians blindly administer them to patients in two groups of case and control. After data gathering, they will be analyzed blindly.

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
Elm va Fanavari Shahrak, In the end of Shahid Fakouri

Blvd. (In front of Fakouri 94)

City
Mashhad

Province
Razavi Khorasan

Postal code
91778-99191

Approval date
2020-11-21, 1399/09/01

Ethics committee reference number
IR.MUMS.REC.1399.311

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code
J45

ICD-10 code description
Asthma

Primary outcomes

1

Description

Investigation of preventive effect of probiotic nasal spray in incidence of upper respiratory infection

Timepoint

Every two weeks until one month

Method of measurement

Checklist of signs and symptoms

2

Description

Axillary temperature above 38 Celsius degree

Timepoint

Every two weeks until one month

Method of measurement

Mercury thermometer placed in axillary space

3

Description

Exacerbation of Respiratory symptoms

Timepoint

Every two weeks until one month

Method of measurement

Checklist of symptoms

4

Description

Development of gastrointestinal symptoms

Timepoint

Every two weeks until one month

Method of measurement

Checklist of symptoms

5

Description

Abnormality in smell or gestatory senses

Timepoint

Every two weeks until one month

Method of measurement

Checklist of symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: probiotic nasal spray, which administer twice daily, one puff in each nostril, for one month. Lactobacillus reuteri and lactobacillus casei strains will cultured in 37 centigrade degree in 24 hours. then they will be centrifuged and with adding isotonic sodium chloride, 10 8 CFU/ ml concentration will be obtained. with appropriate ratio of glucose and fructose, we will enhance probiotic growth. after heating of solution, we culture it again and confirm obtaining heated and lysate probiotic nasal spray.

Category

Prevention

2

Description

Control group: rhinosalin nasal spray, which administer twice daily, one puff in each nostril, for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar children's hospital

Full name of responsible person

Nasrin Moazzen

Street address

Kaveh street

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moazzenn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research and technology office of Mashhad university of medical sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Shahrak Danesh va Salamat, Shahid Fakouri Blvd.

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Grant name

Office of Research and Technology, mashhad university of medical sciences

Grant code / Reference number

990245

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

research and technology office of 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

Nasrin Moazzen

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

Street address

Akbar children' s hospital, shahid Kaveh Blvd, in front

of No 14 Kaveh street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nasrin Moazzen

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Person responsible for updating data

Contact

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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