

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of glutamine supplementation on serum levels of some inflammatory factors, oxidative stress, and appetite in children with respiratory infection 2-6 years

Protocol summary

Study aim

Determining the effect of glutamine on serum levels of inflammatory factors and oxidative stress in children with lower respiratory tract infection

Design

The placebo-controlled clinical trial, with parallel, double-blind, randomized groups on 40 patients. A Randomized block design and random allocation software (RAS) will be used for randomization.

Settings and conduct

This study will be conducted on 40 children aged 2-6 years with lower respiratory infection referred to Bu Ali Hospital, Ardabil, Iran. Subjects will be randomly allocated into glutamine and placebo groups. At the baseline, general information will be collected from each participant. Blood samples (2cc) will be collected from each patient for measurement of study outcomes. Then, the intervention group will receive a glutamine supplement of 0.5 g / kg with a tablespoon of sugar and the placebo group will receive the same amount of sugar. Evaluation of symptoms and blood sampling to measure biochemical parameters will be repeated at the end of the intervention period for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 2-6 years old, having a respiratory infection, and willingness to cooperate. Exclusion criteria: unwilling to participate in the study, the presence of chronic disease

Intervention groups

The intervention group will receive a 0.5 g/kg BW glutamine supplement with a tablespoon of sugar for five days. The placebo group will receive a tablespoon of sugar for five days.

Main outcome variables

IL1 β , tumor necrosis factor-alpha, malondialdehyde, total antioxidant capacity, and Appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210913052455N1**

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

Registration timing: **prospective**

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

Update count: **0**

Registration date

2021-09-24, 1400/07/02

Registrant information

Name

Vahideh Aghamohammadi

Name of organization / entity

Khalkhal faculty of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3242 6801

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v_agamohammadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of glutamine supplementation on serum levels of some inflammatory factors, oxidative stress, and appetite in children with respiratory infection 2-6 years

Public title

The effect of glutamine supplementation in children with respiratory infection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 2 to 6 years Having a respiratory infection
Willingness to cooperate

Exclusion criteria:

Unwilling to cooperate Existence of chronic disease

Age

From 2 years old to 6 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to the glutamine and placebo groups by randomized block design and using random allocation software (RAS, link: <https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-4-26>), participants in each block will be matched by gender and age. To achieve blinding the volume of each block will be considered 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The supplement and placebo Containers will be coded by the researcher as A and B and then will be distributed to patients by a staff member who has no clinical role in the study and is unaware of the contents of the containers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Khalkhal Faculty of Medical Sciences

Street address

Shahid Mozaffar Azizi

City

Khalkhal

Province

Ardabil

Postal code

5681761351

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.ARUMS.REC.1398.122

Health conditions studied

1

Description of health condition studied

Respiratory infection

ICD-10 code

CA4Z

ICD-10 code description

Lung infections, unspecified

Primary outcomes

1

Description

Interleukin 1 beta (IL-1B)

Timepoint

At the baseline of the study and after 5 days intervention

Method of measurement

Standard kit

2

Description

Tumor necrosis factor-alpha

Timepoint

At the baseline of the study and after 5 days intervention

Method of measurement

standard kit

3

Description

malondialdehyde

Timepoint

At the baseline of the study and after 5 days intervention

Method of measurement

standard kit

4

Description

total antioxidant capacity

Timepoint

At the baseline of the study and after 5 days intervention

Method of measurement

standard kit

5**Description**

Appetite

Timepoint

At the baseline of the study and after 5 days intervention

Method of measurement

The Appetite and Diet Assessment Tool

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Glutamine group will receive 0.5g/kg body weight with one tablespoon sugar daily for 5 days

Category

Treatment - Drugs

2**Description**

Control group: placebo group will receive one tablespoon sugar daily for 5 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bu Ali hospital, Ardabil

Full name of responsible person

Ali Nemati

Street address

Sports Square, Moallem Street , Opposite to Azadi Park , Bouali Educational and Medical Center, Ardabil, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

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

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Ali Nemati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Assistant professor

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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