Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effectiveness of oral compounds derived from Organosulfur as the treatment in pediatrics with pneumonia.

Protocol summary

Study aim
The effectiveness of compounds derived from organosulfur in the treatment of children with pneumonia hospitalized in Akbar Mashhad Hospital

Design
A clinical trial with the control group, with parallel groups, three-blind, randomized, stratified, phase 3 on 70 intervention patients and 70 control patients, for randomization using www.randomization.com

Settings and conduct
Children with pneumonia symptoms are admitted to Akbar Mashhad Hospital (lung, infectious, and PICU). Patients are randomly divided into intervention and control groups. Blinding is done in clinical assessors, data analyzers, and data collectors.

Participants/Inclusion and exclusion criteria
Criteria for entering : • Patients aged 3 to 16 years • The patient does not need a ventilator • A patient with pneumonia Criteria for not entering : - History of allergy to allicin-L-cysteine - History of allergy to garlic and onion -History of hypotension or gastrointestinal bleeding - Low blood pressure of the patient at the beginning of the study (below 120/80) - Patients with immune deficiency - The patient's inability to swallow oral medication that has not been inserted into an NG tube or other delivery method for any reason.

Intervention groups
intervention group: In the intervention group, for children aged 3 to 7 years, Nicovid capsules derived from organosulfur containing 0.25 mg of the active ingredient were given every 12 hours for 7 days, and for children over 7 years of age, capsules containing 0.25 mg of the active ingredient were given every 8 hours. Once for 7 days Control group (placebo): In the control group, placebo administration (capsules similar to the capsules of the intervention group with neutral execution and maltodextrin combination) for 7 days

Main outcome variables
SpO2 ، CRP ، LDH ، D-dimer ، Ferritin ,CBC, ESR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221129056657N2**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-05, 1401/12/14**
Update count: **1**

Registration date
2023-01-25, 1401/11/05

Registrant information

Name
Gholamreza khademi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3189 1780

Email address
khademigh@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of oral compounds derived from Organosulfur as the treatment in pediatrics with pneumonia.

Public title
Investigating the effect of organosulfur compounds on children's lung infections
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient age 3 to 16 years The patient does not need a ventilator A patient with pneumonia and hospitalized in the special care, infectious and lung department
Exclusion criteria:
History of allergy to allicin-L-cysteine History of allergy to garlic and onion Patients with a history of hypotension or gastrointestinal bleeding Low blood pressure of the patient at the beginning of the study (below 120/80) Immune compromised patients - under chemotherapy, organ and bone marrow transplantation, and patients with autoimmune diseases The patient's inability to swallow oral medication that is not embedded in the NGtube or other delivery method.
Age
From **3 years** old to **16 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Individual simple randomization Random number table randomization tool using www.randomization.com Allocation Concealment method: envelopes closed In this method, first, a random sequence is created, then based on the size of the research sample, a number of envelopes with aluminum wrappers (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the generated random sequences is recorded on a card, and the cards are inside The letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
For blinding, ICU nurses, ICU doctors, patient treatment physicians, laboratory experts, radiology experts, statistical consultants, and data analysts were unaware of the patient's randomization and placement in the therapy group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Committee on Ethics in Research, Faculty of Medicine, Mashhad University of Medical Sciences
Street address
Qurashi Building، Daneshgah Street,Mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177897157
Approval date
2022-11-22, 1401/09/01
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.524

Health conditions studied

1

Description of health condition studied
Pneumonia
ICD-10 code
J18.0
ICD-10 code description
Bronchopneumonia, unspecified organism

Primary outcomes

1

Description
Fever
Timepoint
The first day of the study before the start of the intervention and the seventh day of the study (the last day of the intervention)
Method of measurement
Digital thermometer

2

Description
blood oxygen (SpO2)

Timepoint
The first day of the study before the start of the intervention and the seventh day of the study (the last day of the intervention)
Method of measurement
Pulse Oximeter

3

Description
Erythrocyte Sedimentation Rate (ESR)
Timepoint
The first day of the study before the start of the intervention and the seventh day of the study (the last day of the intervention)
Method of measurement
Westergren method

Secondary outcomes

1

Description
blood pressure
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention
Method of measurement
Mercury sphygmomanometer

2

Description
heart beat
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention
Method of measurement
Pulse oximeter

3

Description
Blood gases
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention.
Method of measurement
Blood gas measuring device

4

Description
C reactive protein
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention.
Method of measurement
Taking blood samples and laboratory kits

5

Description
Lactate dehydrogenase
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention.
Method of measurement
Electrophoresis method

6

Description
D-dimer
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention.
Method of measurement
Using Vidas laboratory kit

7

Description
complete blood count(CBC)
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention.
Method of measurement
Blood cell counting machine

8

Description
Ferritin
Timepoint
At the beginning of the study (before the start of the intervention) and on the seventh day after the start of the intervention.
Method of measurement
Use of ELISA laboratory kit(Enzyme-linked immuno_sorbent assay)

Intervention groups

1

Description
Intervention group: Capsules derived from organosulfur (Nicovid capsules are ordered by Surin Salamat Sabz Tehran Company and produced by Esveh Pharmaceutical Company. Each capsule contains standardized organosulfur of garlic extract based on: Allicin, L-Cysteine, L-Methionine, Maltodextrin, and Vanilla.), containing 0.25 mg of the active ingredient, for children three to seven years old every 12 hours for 7 days and for children over 7 years old every 8 hours Duration of 7 days.
Category
Treatment - Drugs

2

Description
Control group: Administration of placebo (capsules similar to those of the intervention group with neutral implementation and maltodextrin combination) for children three to seven years old every 12 hours for 7 days and for children over 7 years old every 8 hours for 7 days.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbar Children's Hospital

Full name of responsible person
Gholamreza Khademi

Street address
Akbar Children's Hospital, Shahid Kaveh Boulevard

City
Mashhad

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Email
khademigh@mums.ac.ir

Web page address
https://akbar.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hossein Niktale - the inventor of medicine

Full name of responsible person
Mohammad Rasool Gholampour - Accelerator

Street address
Unit 14- No. 19- West Taban Alley- Nelson Mandela Street-Tehran

City
Tehran

Province
Tehran

Postal code
13944 -91388

Phone
+98 912 521 7885

Email
hoseen.nikta@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Hossein Niktale

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Gholamreza Khademi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Akbar Children's Hospital-Shahid Kaveh Boulevard - Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Gholamreza Khademi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Position
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Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Part of the data related to the main outcomes
When the data will become available and for how long
Six months after the results are published
To whom data/document is available
Academic institutions
Under which criteria data/document could be used
For the purpose of research for the academic community
From where data/document is obtainable
Dr. Gholamreza Khademigh Khademigh@mums.ac.ir
What processes are involved for a request to access data/document
The request will be sent by email to Dr. Gholamreza Khademi after correspondence about two weeks after the registration of the data request.
Comments