Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the clinical course and consequences of disease in the children suspicious to Covid-19 who have/have not received Antibiotics

Protocol summary

Study aim

Evaluation of the clinical course and consequences of disease in the children suspicious to Covid-19 who have/have not received Antibiotics

Design

This is a clinical trial study with control group, double blind , randomized with software allocation random software.

Settings and conduct

70 patients with suspected Covid 19 will be selected. Patients are between 2 and 14 years old. Then the patients are divided into two groups of 35. The first group (control) received routine treatment. Gram for each kilogram is prescribed every 8 hours for at least 7 days. During the review of the file and the clinical course of the patients, the group started with antibiotics and the group with similar symptoms, the antibiotics were not started for the patient. In case of any evidence that children need antibiotic treatment, they will be excluded from the study. Patients' clinical signs and inflammatory tests are recorded on the first and seventh day

Participants/Inclusion and exclusion criteria

Participants: Patients suspected of having Covid 19 with approved molecular test admitted to Hajar Hospital in Shahrekord In the year 1400 ; Inclusion criteria: confirmed molecular test; Patient with positive IgM test; Exclusion criteria: History of any underlying disease; the patient needs antibiotics; Dissatisfaction of the patient and his family;

Intervention groups

Intervention group: receiving routine treatment + antibiotic cephalosporins (cefotaxime) and injectable at a dose of 50 mg / kg every 8 hours for at least 7 days
Control group: Routine treatment (serum therapy, acetaminophen, etc.)

Main outcome variables

Age, sex, respiratory rate, inflammatory tests, duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220116053739N1**
Registration date: **2022-04-15, 1401/01/26**
Registration timing: **retrospective**

Last update: **2022-04-15, 1401/01/26**
Update count: **0**

Registration date

2022-04-15, 1401/01/26

Registrant information

Name

Maryam Mohsenifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 5833

Email address

amin_mohsenifar@auto.iust.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-28, 1400/07/06

Expected recruitment end date

2022-01-26, 1400/11/06

Actual recruitment start date

2021-09-28, 1400/07/06

Actual recruitment end date

2022-03-30, 1401/01/10

Trial completion date

empty

Scientific title

Evaluation of the clinical course and consequences of disease in the children suspicious to Covid-19 who have/have not received Antibiotics

Public title

Evaluation of the clinical course and consequences of disease in the children suspicious to Covid-19 who have/have not received Antibiotics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient with IgM positive The patient with confirmed molecular test

Exclusion criteria:

Having the background of Underlying disease Any clinical or laboratory evidence of the patient need for Antibiotics Lack of consent of the patient and his/her family for the participation in the study

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Actual sample size reached: **101**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants have been randomly distributed to the control and experimental groups using Random Allocation Software

Blinding (investigator's opinion)

Double blinded

Blinding description

In selecting the envelopes, neither the participant nor the researcher is not aware of the envelope content and an envelope is randomly selected for each patient. After selecting an envelope, the parents of the patient are informed if the patient had received Antibiotic or not. Even the researcher was not informed of that. The number of participants in the study was considered to be envelopes with numbers 1 to 70 and using the software, the number 0 or 1 was randomly assigned to each envelope, and the number zero means not receiving antibiotics and the number 1 It means taking antibiotics

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

somaheh Blvd.

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814873588

Approval date

2021-09-28, 1400/07/06

Ethics committee reference number

IR.SKUMS.REC.1400.145

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Covid 19

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

Time of discharge from the hospital

Method of measurement

Number of days hospitalized

2

Description

Complete blood count (CBC)

Timepoint

Day of hospitalization, seven days after hospitalization

Method of measurement

Use of cell counting machine

3

Description

Fever

Timepoint

Day of hospitalization, seven days after hospitalization

and One month after hospitalization

Method of measurement

Thermometer

4

Description

Cough

Timepoint

Day of hospitalization, seven days after hospitalization and One month after hospitalization

Method of measurement

Asking the patient

Secondary outcomes

1

Description

Test result of Troponin

Timepoint

Day of hospitalization and seven days after hospitalization

Method of measurement

Troponin test kit

2

Description

D-dimer

Timepoint

Day of hospitalization and seven days after hospitalization

Method of measurement

Latex agglutination test

3

Description

Erythrocyte Sedimentation Rate (ESR)

Timepoint

Day of hospitalization and seven days after hospitalization

Method of measurement

The Westergren method

4

Description

C-reactive protein test (CRP)

Timepoint

Day of hospitalization and seven days after hospitalization

Method of measurement

Latex agglutination test

5

Description

Anorexia

Timepoint

Day of hospitalization, seven days after hospitalization and One month after hospitalization

Method of measurement

Asking the patient

Intervention groups

1

Description

Patients in the intervention group were treated with a group of antibiotics with gram-negative and gram-positive coverage (third generation cephalosporin). Third-generation cephalosporins include cefotaxime (from Eixir Pharmaceutical Company) as an injection at a dose of 50 mg per kg every 8 hours for at least 7 days. Also in this group, the routine hospital care intervention intended for the control group included serum therapy (including normal saline serum, one-third and two-thirds serum), and the use of antipyretics (acetaminophen at a dose of 10 mg per kg). It was administered orally or by injection in patients with a body temperature of more than 38 with an interval of at least 6 hours.

Category

Treatment - Drugs

2

Description

In the control group, patients did not receive any antibiotics and routine hospital care included serum therapy (including normal saline, one-third and two-thirds serum), and the use of antipyretics (acetaminophen at a dose of 10 mg per kg). Received orally or by injection in patients with a body temperature greater than 38 (at least 6 hours apart) during hospitalization.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital of Shahrekord

Full name of responsible person

Maryam Mohsenifar

Street address

parastar street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8814873588

Phone

+98 38 3222 0016

Email

info@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghi
Street address
Kashani Blvd., the headquarters of Shahrekord University of Medical Sciences
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3222 0016
Email
vcrt@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahrekord University Medical Science
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Maryam Mohsenifar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Somaheh Blvd.
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8814873588
Phone
0983833335833
Email
amin_mohsenifar@outlook.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Nabiollah Asadpour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Parastar Street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3333 0061
Email
n.asadpour@skums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Maryam Mohsenifar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Somaheh Street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8814873588
Phone
+98 38 3333 5833
Email
amin_mohsenifar@outlook.com

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