Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Evaluation of the effect of N-acetyl cysteine on the prognosis of hospitalized children with covid 19 : a pilot-randomized-double blinded-placebo-controlled clinical trial

Protocol summary

Study aim
according to the limitation of using drugs in children with covid-19 and in the other hand safety of NAC and the good effects of this drug in adults ,if we get positive result we can use this drug in a large number of children.

Design
this clinical trial has a control group with parallel groups , double blinded , randomized , on 40 patients , we will use https://www.sealedenvelope.com for randomization.

Settings and conduct
the trial will performed at 17 shahrivar hospital in rasht , the trial will performed at two groups of intervention and control , participants , doctors and nurses will be blind and they will not know the wich patient takes NAC which one takes placebo.

Participants/Inclusion and exclusion criteria
entry requirements : every child with 8 to 18 ages of year with clinical diagnosis of covid including positive PCR test and chest radiography coming to 17 sahrivar hospital in rasht. no entry condition : parents or patients dissatisfaction for participating in study ,patients with severe covid or patients who hospitalized in ICU

Intervention groups
the first group receives 600mg of NAC (effervescent tablets of osweh company) twice a day and second group receives placebo effervescent tablets(osweh company) twice a day by enteral method , the duration of receiving the intervention is 7 days.

Main outcome variables
duration of need to ventilator and improvement of clinical symptoms and inflammatory factors (CRP) , hospitalized in intensive care unit and patients condition at discharge.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054879N1**
Registration date: **2022-06-11, 1401/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-11, 1401/03/21**
Update count: **0**

Registration date
2022-06-11, 1401/03/21

Registrant information

Name
maryam shahrokhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3336 9026

Email address
mshahrokhi@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-31, 1401/03/10

Expected recruitment end date
2022-12-01, 1401/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of N-acetyl cysteine on the

prognosis of hospitalized children with covid 19 : a pilot-randomized-double blinded-placebo-controlled clinical trial

Public title
Evaluation of the effect of N-acetyl cysteine on the prognosis of hospitalized children with covid 19 : a pilot-randomized-double blinded-placebo-controlled clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
every child with 8 to 18 ages of year with clinical diagnosis of covid including positive PCR test and chest radiography coming to 17 sahrivar hospital in rasht.

Exclusion criteria:
parents or patients dissatisfaction for participating in study patients with severe covid or patients who hospitalized in ICU

Age
From **8 years** old to **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
in this study the patients will randomized with blocking randomization , with ratio of 1:1 . after that they will divided to 2 groups. 30 people of children with age of under 18 with covid will divided to 2 groups which are intervention and control , A and B.

Blinding (investigator's opinion)
Double blinded

Blinding description
the groups of patients will determine after randomization , participants and doctors who are responsible for health of children are blind on this study , also radiologists , evaluating researchers and statistics specialist will be blind in the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences

Street address
Deputy of research and Technology, In front of 17 Shahrivar Hospital, Shahid Siadati Street, Namjoo Street, Rasht

City
Rasht

Province
Guilan

Postal code
4193713111

Approval date
2022-04-06, 1401/01/17

Ethics committee reference number
IR.GUMS.REC.1401.018

Health conditions studied

1

Description of health condition studied
covid 19

ICD-10 code
U07.1

ICD-10 code description
covid-19 , virus identified

Primary outcomes

1

Description
duration of need to ventilator

Timepoint
desired factor will measure at first of hospitalization then after 7 days or at the time of discharge.

Method of measurement
the prognosis of patients with time of hospitalization and the period of time need to ventilator and status at the time of discharge will evaluate.

2

Description
improvement of clinical signs and oxygenation

Timepoint
desired factor will measure at first of hospitalization then after 7 days or at the time of discharge.

Method of measurement
the prognosis of patients with time of hospitalization and the period of time need to ventilator and status at the time of discharge will evaluate.

3

Description
CRP inflammatory factor
Timepoint
desired factor will measure at first of hospitalization then after 7 days or at the time of discharge.
Method of measurement
the prognosis of patients with time of hospitalization and the period of time need to ventilator and status at the time of discharge will evaluate.

4

Description
Hospitalization in the intensive care unit
Timepoint
will be checked if transfer occur
Method of measurement
the prognosis of patients with time of hospitalization and the period of time need to ventilator and status at the time of discharge will evaluate.

5

Description
patient status at discharge
Timepoint
at the discharge
Method of measurement
the prognosis of patients with time of hospitalization and the period of time need to ventilator and status at the time of discharge will evaluate.

Secondary outcomes

1

Description
secondary variable is patient status at the time of discharge(recovery)
Timepoint
at the discharge
Method of measurement
order and diagnosis of pediatrician

2

Description
secondary variable is patient status at the time of discharge (transfer to the intensive care unit or death)
Timepoint
at the discharge or transfer
Method of measurement
order and diagnosis of pediatrician

Intervention groups

1

Description
Intervention group: in this trial we will use effervescent tablets of NAC from osveh company with dose of 600 mg BD , duration of prescription is 7 days or until discharge.
Category
Treatment - Drugs

2

Description
Control group: in this group we will use effervescent placebo of NAC (osveh company) BD (twice in a day) for 7 days or until discharge.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Hospital
Full name of responsible person
Maryam Shahrokhi
Street address
17 Shahrivar Hospital, Shahid Siadati Street, Namjoo Street, Rasht
City
Rasht
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Guilan
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4144654379
Phone
+98 13 3336 9019
Fax
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Email
17shahrivar@gums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Naghipour
Street address
In front of 17 Shahrivar Hospital, Shahid Siadati Hospital, Namjoo Street, Rasht
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Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Maryam Shahrokhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Email

17shahrivar@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Maryam Shahrokhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Pouria Seifnezhad

Position

Pharmacy Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Unit 2, Kian Apartment, 175 Street, Guilan Boulvar, Golsar, Rasht

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4166743374

Phone

+98 13 3377 4513

Email

pouria_seifnezhad@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

attention to patients privacy and also ethical principles.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

results of this clinical trial will be available , private information will be available just for treatment staff , for the privacy of patients , the patients information will reserved near researcher.

When the data will become available and for how long

there is no program to publication till now , but if we want to publish it will be 6 months after result.

To whom data/document is available

researchers working on this field , pediatricians and educated doctors for reaching our datas.

Under which criteria data/document could be used

doctors and researchers can receive the data , limitation is patient privacy and medical ethics.

From where data/document is obtainable

Dr maryam shahrokhi - 17 shahrivar hospital -Rasht pharmacy faculty , guilan university of medical sciences , pouria seifnezhad

What processes are involved for a request to access data/document

coming to 17 shahrivar hospital in rasht and signing the form then visiting the mail researcher of the trial and investigate the request - then consultation with medical ethics committee and after that giving the data

Comments