

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### **Province**

Guilan

##### **Postal code**

4144654379

##### **Phone**

+98 13 3336 9019

##### **Fax**

+98 13 3336 9262

##### **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

##### **City**

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##### **Province**

Guilan

##### **Postal code**

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##### **Phone**

+98 13 3333 6394

##### **Fax**

+98 13 3333 6395

##### **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

**Street address**

17 Shahrivar Hospital, Shahid Siadati Street, Namjoo Street, Rasht

**City**

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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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17shahrivar@gums.ac.ir

**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

**City**

Rasht

**Province**

Guilan

**Postal code**

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**