# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## Evaluation of the protective effect of a combination drug including Apocynin, Niacin, and Tannin on prevention of cardiovascular and respiratory morbidities and mortality in COVID-19 infection: A Clinical Trial

## Protocol summary

**Study aim**
To evaluate the respiratory and cardiovascular morbidities in the experimental group with daily consumption of Tannin-Niacin-apocynin in affected patients by coronavirus infection

**Design**
In phase II, at first, 5 patients with non-serious presentations are included in a pilot-study with informed consent. The current-treatments are given to the patients in an open-labeled-approach and the combination drug is added on their treatment. If the results are approved the trial will continue with more patients up to 20% of all experimental-cases. If the results are approved again, the study will continue on all the cases according to the following statement.

**Settings and conduct**
80 patients confirmed for COVID-19 are recruited into two groups through the permuted block randomization approach. Each group included 40 cases.

**Participants/Inclusion and exclusion criteria**
Inclusion-criteria: Age more than 18 years, Clinical and paraclinical signs and symptoms for COVID19, inpatient-setting, Positive-PCR, Informed-consent Exclusion-criteria: Pregnancy, hx of using ACEI and ARB-drugs, fludrocortisone, spironolactone, eplerenone, TCA, Simvastatin, MAO-inhibitors, serotonin-inhibitors, Triptamins, Alcoholism, Heart-Failure, Hepatic-Failure, renal-dysfunction, drug side-effects, Active-peptic-ulcer, Active-Bleeding

**Intervention groups**
Experimental group includes inpatient COVID19cases with mild-to-moderate respiratory problems that are confirmed for corona infection. They give current treatment plus the three-drug combination of trial. Control group includes the COVID19patients with mild-to-moderate respiratory problems that will be treated just by current-treatment.

**Main outcome variables**
Primary outcomes: Fever, PR, RR, BP Dyspnea O2 sat ICU dependency Ventilation-dependency inpatient-period Mortality Secondary outcomes: 28days-survival Re-hospitalization Clinical symptoms

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200418047122N1**
Registration date: **2020-05-03, 1399/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-03, 1399/02/14**
Update count: **0**

**Registration date**
2020-05-03, 1399/02/14

**Registrant information**

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Mehrdad Zeinalian

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-04-25, 1399/02/06

**Expected recruitment end date**

2020-05-21, 1399/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the protective effect of a combination drug including Apocynin, Niacin, and Tannin on prevention of cardiovascular and respiratory morbidities and mortality in COVID-19 infection: A Clinical Trial

**Public title**

Evaluation of the therapeutic effect of a combination drug including Apocynin, Niacin, and Tannin on COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age more than 18 years Clinical and paraclinical signs and symptoms for COVID19-induced pneumonia inpatient setting Positive PCR for COVID19 Informed consent

**Exclusion criteria:**

Pregnancy A recent medical history of using ACEI and ARB drugs, fludrocortisone, spironolactone, eplerenone, TCA antidepressant, Simvastatin, MAO inhibitors, serotonin inhibitors such as sertraline and citalopram, Triptamins, Alcoholism Heart Failure (EF<25%) Hepatic failure (Child Pugh score ≥ C ,AST> 5 times of the upper limit normal) Severe renal dysfunction (GFR less than 30cc per min) Any drug side-effects including: Patients' intolerance, Diarrhea, Gastrointestinal problems Active peptic ulcer Active Bleeding

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Altogether, 80 patients confirmed for COVID-19 are recruited into two groups through permuted block randomization approach. The block size will be considered of size 4. Each group included 40 cases and 40 controls.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Institutional Research Ethics Committee, School of Medicine, Isfahan University of Medical Sciences

**Street address**

School of Medicine, Isfahan University of Medical Sciences, Hezar-Jarib Ave

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174673461

**Approval date**

2020-04-19, 1399/01/31

**Ethics committee reference number**

IR.MUI.MED.REC.1399.050

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19-induced pneumonia

**ICD-10 code**

U07.01

**ICD-10 code description**

COVID-19

## Primary outcomes

### 1

**Description**

Fever

**Timepoint**

BID

**Method of measurement**

Thermometer

### 2

**Description**

Hemodynamic signs

**Timepoint**

BID

**Method of measurement**

P/E

**3**

**Description**
O2 sat
**Timepoint**
BID
**Method of measurement**
Puls-Oximetery

**4**

**Description**
Clinical symptomes
**Timepoint**
TDS
**Method of measurement**
P/E and medical hx

## Secondary outcomes

**1**

**Description**
Drug side-effects
**Timepoint**
Continuous
**Method of measurement**
PE and MH

**2**

**Description**
Survival and clinical symptoms
**Timepoint**
Continuous
**Method of measurement**
PE and MH

## Intervention groups

**1**

**Description**
Intervention group: This group includes inpatient cases with mild to moderate respiratory problems that are confirmed for corona infection. In phase II non-randomized clinical trial, at first, 5 patients confirmed with COVID-19 and non-serious presentations are included in a pilot study from which informed consents have been gotten. The current standard treatments are given to the patients in an open-labeled approach and combinative drug including: two capsules and two spoonfuls of syrup per day including Niacin-Tannin in capsule and Apocynin in syrup with Bid consumption of Tannin(125mg) + Niacin(5mg) and one spoonful apocynin (2.5mg) up to 14 days. The control group only receives current treatment. . Then the side-effects and efficacies will be evaluated. If no side-effects are observed and therapeutic outcomes are positive, the results will be reported to the RCT assessment committee. If the permission is given, the trial will continue with more patients up to 20% of all experimental cases. Then the evaluation will be repeated. If the results are approved again, the study will continue on all the cases according to the following statement. In this clinical trial we will finally recruit 80 patients infected by COVID19 in two groups of experimental and control. Except in the pilot phase that the control group is not included, in the following, the control group will be also added with just standard treatment until 14 days follow-up and clinical assessment. If a patient is discharged from the hospital, his/her follow-up of the treatment and clinical evaluation will continue at home via daily interview by phone. The necessary education will be presented for all the patients and their families before discharging.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: This group includes the patients with mild to moderate respiratory problems that are confirmed for Corona infection
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Amin Hospital
**Full name of responsible person**
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**2**

**Recruitment center**
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## Sponsors / Funding sources

**1**

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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**
Esfahan 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**
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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**
No - There is not 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**
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