

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

Name

Mehrdad Zeinalian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9196

Email address

m.zeinalian@med.mui.ac.ir

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 \geq 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

Isfahan

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-Oximetry

4

Description

Clinical symptoms

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

Dr Pourajam

Street address

Ebne-Sina Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3445 5055

Email

spourajam@gmail.com

2

Recruitment center**Name of recruitment center**

Noor Hospital

Full name of responsible person

Dr Shirani

Street address

Bagh-Goldasteh Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2127

Email

zeinalianmehrddad@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Tahereh Changiz

Street address

Hezar-Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 9196

Email

zeinalianmehrddad@gmail.com

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**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Hossein Khanahmad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

Street address

Hezar Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 9197

Email

hossein_khanahmad@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Hossein Khanahmad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

Street address

Hezar-Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 9197

Email

hossein_khanahmad@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mehrdad Zeinalian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Hezar-Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 9196

Email

zeinalianmehrddad@gmail.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

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