Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ≥ 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
Dr Pourajam
Street address
Ebne-Sina Ave
City
Isfahan
Province
Isfehan
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
Isfehan
Postal code
8174673461

Phone
+98 31 3222 2127
Email
zeinalianmehrdad@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
Isfehan
Postal code
8174673461
Phone
+98 31 3792 9196
Email
zeinalianmehrdad@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
Isfehan
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
Isfehan
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
Isfehan
Postal code
8174673461
Phone
+98 31 3792 9196
Email
zeinalianmehrdad@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