Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of Ionic Plasma Cluster Technology on the improvement of symptoms in patients with COVID-19

Protocol summary

Study aim
Identifying the role of plasma cluster in the alleviation of symptoms in Covid-19 patients

Design
A control group with parallel groups, two-way blind, goal-based, phase 2 on 60 patients is included in the clinical investigation.

Settings and conduct
Outpatients with Covid-19 who do not require oxygen were referred to a specialist clinic for infectious illnesses in Bojnourd, as well as 16-hour Covid-19 testing centers.

Participants/Inclusion and exclusion criteria
Patients with mild to moderate Covid-19 symptoms who have had symptoms for at least 7 days and are between the ages of 18 and 50 should complete an informed consent form.

Intervention groups
After obtaining the code of ethics from the research ethics committee of North Khorasan University of Medical Sciences and also the code of clinical trial of researchers by referring outpatients with Covid-19 referred to the specialized clinic of infectious diseases and 16-hour test centers of Covid-19 in Bojnourd By identifying all patients who with initial diagnosis of Covid-19 (based on clinical signs) who are eligible for home quarantine will be included in the study (the sampling method will be accessible and purposeful). Patients will begin treatment and be referred for PCR at the same time. If the test is negative, the patient is excluded from the study. Then 60 patients who meet the inclusion criteria will be included in the study and will be divided into two groups (intervention group (receiving plasma cluster and routine treatment are 30 people) and control group (routine treatment are 30 people)). The plasma cluster device is delivered to the patient with explanations and how to use it and is delivered from the patient for 8 consecutive hours after use.

Main outcome variables
Improving general condition and reducing the severity of symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191111045400N1**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-14, 1400/05/23**
Update count: **0**

Registration date
2021-08-14, 1400/05/23

Registrant information

Name
Mohammad Amin Younesieh Heravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of Ionic Plasma Cluster Technology on the improvement of symptoms in patients with COVID-19

Public title
COVID-19 patients receiving with Ionic Plasma Cluster Technology

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Mild to moderate-grade Covid-19 patients Since the start of their symptoms, a maximum of 7 days have elapsed. Between the ages of 18 and 50, Fill out the informed consent form and sign it.

Exclusion criteria:
Women who are pregnant or breastfeeding Using immunosuppressive medications Using sedatives and serotonin reuptake inhibitors Addiction to drugs underlying illness (chronic kidney and liver disease; brain and heart disease, pulmonary and hypertension; cancer, endocrine and metabolic diseases; thyroid disorders; immune deficiencies, Alzheimer's, multifocal failure, encephalopathy, and neuropathy)

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The study was double-blind so that participants and data analyzers were not aware of the contents of the intervention package.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences

Street address
Shahriyar st, north khorasan university of medical sciences

City
Bojnurd

Province
North Khorasan

Postal code
9417694780

Approval date
2021-06-27, 1400/04/06

Ethics committee reference number
IR.NKUMS.REC.1400.041

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
Covid-19 disease

Primary outcomes

1

Description
Improve symptoms based on checklist

Timepoint
Patients are monitored before the study and monitored 24 hours after the intervention. Then patients at weekly intervals for 4 weeks after the intervention in terms of clinical improvement by measuring body temperature, cough (zero or mild). And myalgia that is stable for at least 24 hours or the patient is hospitalized.

Method of measurement
Researcher checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 people receiving plasma cluster and routine treatment

Category
Treatment - Other

2

Description
Control group: Routine treatment equal to 30 people
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Special Clinic of Imam Reza Hospital
Full name of responsible person
mohammad amin younesi heravi
Street address
No. 5, North Khorasan University of Medical Sciences, Vice Chancellor for Research and Technology, Shahriar St. Bojnurd. Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Amir Amani
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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
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
mohammad amin younesi
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Radiology
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Position
Assistant Professor
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Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Salar Poorbarat

Position
Employee

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
There is no more information

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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available