

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Administration of Zinc-Chelating Agents (intravenously CaNa₂EDTA) in COVID-19 Patients: A pilot study

Protocol summary

Study aim

Evaluation of blood cells, blood pressure, blood oxygen, albumin, total protein, ALT, AST, ALP, LDH, LDL, HDL, Cholesterol, Triglyceride, CRP, Pro-Calcitonin, IL-6, Pro-BNP, D-dimer, in patients receiving EDTA and control group

Design

In this study, 100 people who are divided into two groups of control and treatment will enter the study. And are categorized completely randomly.

Settings and conduct

The prescribing strategy is based on the minimum effective dose for each patient in Ghaem Asadabad Hospital. In order to tailoring of medical treatment to the individual characteristics of each patient (precision medicine) and to avoid adverse effects, an administration strategy based on the minimal effective dose (which can be different depending on the patient and disease condition) for each patient will be pursued. To this aim, it is proposed to start with 100 mg/m² every 8 hours (3 times a day).

Participants/Inclusion and exclusion criteria

The study population is the total number of patients admitted to the Intensive Care Unit (ICU) of Ghaem Hospital, Asadabad, who was admitted to that ward due to respiratory distress caused by Covid-19 disease. After the researchers explain the goals of the project, the patients who sign the consent will enter the research. Exclusion criteria included diabetic patients taking insulin, patients with urinary tract problems, patients with cardiovascular problems, and people who did not sign the consent form.

Intervention groups

Control group: Receiving common medications for Covid-19 in the ICU
Treatment group: Receiving common drugs for Covid-19 in the ICU + a dose of 50 to 100 mg of calcium EDTA three times a day intramuscularly or intravenously for 2-3 days and 5 days if needed

Main outcome variables

Improve oxygen supply

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210913052453N1**

Registration date: **2021-11-08, 1400/08/17**

Registration timing: **retrospective**

Last update: **2021-11-08, 1400/08/17**

Update count: **0**

Registration date

2021-11-08, 1400/08/17

Registrant information

Name

hemen moradi-sardareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3313 2015

Email address

hemen.moradi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Administration of Zinc-Chelating Agents (intravenously CaNa2EDTA) in COVID-19 Patients: A pilot study

Public title

"The chelating effect of zinc in patients with Covid 19"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Covid-19 admitted to the Intensive Care Unit (ICU) Patients with Covid-19 with respiratory distress

Exclusion criteria:

insulin-dependent diabetic patients Patients with urinary tract disorders Patients with cardiovascular system disorders

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization tool: Random number table
Random number table is a set of numbers that are produced without a specific pattern or order and in a completely random form and has become a table. In order to use the table of random numbers, we first predetermined the table to read the numbers (for example, up, down, left or right), then we assumed that the numbers should be used for different study groups.

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

Ethics committee of asadabad school of Medical Sciences

Street address

22 bahman Blvd, asadabad city

City

Asadabad

Province

Hamadan

Postal code

6541743896

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.ASAUMS.REC.1400.010

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

2

Description of health condition studied

covid-19

ICD-10 code

R06.0

ICD-10 code description

Dyspnea

3

Description of health condition studied

covid-19

ICD-10 code

R05

ICD-10 code description

Cough

4

Description of health condition studied

covid-19

ICD-10 code

J12.81

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description

blood oxygenation

Timepoint

At the beginning of the study, and 3 days after the study

Method of measurement

Evaluation of blood factors and clinical condition of the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving common drugs for the treatment of Covid-19 in the ICU along with receiving a dose of 50 to 100 mg of calcium EDTA three times a day intramuscularly or intravenously for 2-3 days and if necessary 5 days.

Category

Treatment - Drugs

2

Description

Control group: Receiving common medications for the treatment of Covid-19 in the ICU

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

hemen moradi-sardareh

Street address

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amoozesh@asaums.ac.ir

Web page address

http://asaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Asadabad University of Medical Sciences

Full name of responsible person

Dr.Hosein effatpanah

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Grant name

Research budget of Asadabad School of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Asadabad 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

Asadabad University of Medical Sciences

Full name of responsible person

hemen moradi-sardareh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

If the results of the study are positive for the treatment of patients, the protocol will be reported.

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

All people working in health care centers, and academic and scientific institutions

Under which criteria data/document could be used

There will be no restrictions on the use of data

From where data/document is obtainable

Correspondence with e-mail address

What processes are involved for a request to access data/document

Send an email to the investigator to receive the data clearly stating the reason for receiving the data

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Asadabad University of Medical Sciences

Full name of responsible person

Hemen Moradi-sardareh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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