Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The use of sex hormones in the control of coronavirus inflammation

Protocol summary

Study aim
The effect of injectable estradiol and testosterone in the recovery of acute respiratory, cardiac and renal failure in COVID-19 patients

Design
Clinical trial with control group, with parallel groups, single blinded, and simple randomized, performed on 80 patients. The random number table was used for randomization.

Settings and conduct
In this study, blood serum sample is obtained from 80 COVID-19 patients with respiratory, cardiac, and kidney failure which hospitalized. Testosterone, estrogen, progesterone, and TSH are measured. Afterward, patients are randomized in two groups 40 subjects of case and control (equally in sex). Patients are blinded from the case and control groups. Control group receive common treatment and in intervention group, sex hormones injected to the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: COVID-19 patients with respiratory, heart or kidney failure exclusion criteria: History of breast cancer in females, History of prostate cancer in males, History of thromboembolism in both sexes, suspected breast examination in women, High PSA in primary laboratory tests

Intervention groups
Intervention group: Patients in addition to conventional therapies receive Depo– testosterone vial 200 ng/ml per week in male subjects and Medroxy Progesterone (Depo-Provera) 150mg/ml or progesterone intramuscular injection 60 mg/d per day in female subjects. In case of positive effect on controlling the patient's symptoms and low level of sex hormones in blood sample, it can be repeated every week. Control group: Patients receive common treatment for COVID-19 based on national protocol including Hydroxychloroquine 200 mg UID twice a day, Naproxen 200 mg UID twice a day, Azithromycin 250 per day.

Main outcome variables
Severity of symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150716023235N15**
Registration date: **2020-05-29, 1399/03/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-29, 1399/03/09**
Update count: **0**

Registration date
2020-05-29, 1399/03/09

Registrant information

Name
Farahzad Jabbari Azad

Name of organization / entity
Allergy Research Center, Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 1801 2770

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jabbarif@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The use of sex hormones in the control of coronavirus inflammation

Public title
sex hormones in coronavirus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
COVID-19 patients with respiratory, heart or kidney failure
Exclusion criteria:
History of breast cancer in females History of prostate cancer in males History of thromboembolism in both sexes Suspected breast examination in women High PSA in primary laboratory tests
Age
From **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly divided into two groups using a random number table. Individuals who receive the odd number enter the intervention group, and people with even numbers are placed in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this single-blind study, patients are not aware of the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Ghoreishi building Ethics Committee of Mashahd University of Medical Science
City
Mashhad
Province
Razavi Khorasan
Postal code
9175711111
Approval date
2020-04-29, 1399/02/10
Ethics committee reference number
IR.MUMS.REC.1399.192

Health conditions studied

1

Description of health condition studied
Severity of COVID-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Severity of disease
Timepoint
before intervention and every week until one month
Method of measurement
observation

2

Description
IL-6
Timepoint
before intervention and every week until one month
Method of measurement
Elisa

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: COVID-19 Patients with respiratory, heart, or kidney failure over 50 years of age in addition to conventional therapies received Depo– testosterone vial 200 ng/ml per week in male subjects and Medroxy Progesterone (Depo-Provera) 150mg/ml or progesterone intramuscular injection 60 mg/d per day in female subjects. In case of positive effect on controlling the patient's symptoms and low level in the prepared sample, it can be repeated every week.
Category
Treatment - Drugs

2

Description
Control group: COVID-19 patients with respiratory, heart or kidney failure above 50 years old which received common treatment for COVID-19 based on national protocol including Hydroxychloroquine 200 mg UID twice a day, Naproxen 200 mg UID twice a day, Azithromycin 250 per day.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Farahzad Jabbari-Azad

Street address
Ahmad Abad Ave., Ghaem hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Ghoreishi,Daneshgah Ave, Mashhad

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Ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Farahzad Jabbari-Azad

Position
Professor

Latest degree
Medical doctor

Other areas of specialty/work
Immunology

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Allergy Research Center, Ghaem Hospital , Ahmadabad Ave, Mashhad

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Person responsible for scientific inquiries

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Position
Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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