Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect tocilizumab, plasmapheresis and tocilizumab plasmapheresis combination in Coronavirus disease (COVID -19) patients admitted to the intensive care unit

Protocol summary

Study aim
Evaluation of the therapeutic role of plasmapheresis, tocilizumab and the combination of tocilizumab and Plasmapheresis in patients with covid19

Design
Clinical trial without control group, with parallel group, double-blind, non randomized, phase 3 on 90 patient

Settings and conduct
A total of 90 patients with COVID-19 admitted to the covid19 ward of Yazd Medical Sciences Hospitals who, at the discretion of their treating physician, are candidates for receiving tocilizumab, Plasmapheresis or both. once before and once after the above interventions. Finally, in addition to peripheral and clinical blood parameters according to the questionnaire used, enzyme-linked immunosorbent assay(ELISA) is used to assess the serum levels of cytokines Interleukin 6 (IL-6), Ferritin, procalcitonin, CRP, D Dimer.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 65 years, Detection of Covid-19 based on PCR of the nasopharynx, Serum CRP and interleukin 6 levels are at least twice normal, O2sat <80% without supplemental oxygen or RR> 24 Exclusion criteria: History of drug allergy, Platelets less than 50000, Suspected by active viral (Non-COVID), bacterial and fungal infections, Primary intubation, Pregnancy and lactation, Patient or family dissatisfaction

Intervention groups
the tocilizumab group will receive two doses of 400 mg of tocilizumab (every 24 hours). in the plasmapheresis group undergo three plasmapheresis sessions every 48 hours. in the tocilizumab and plasmapheresis group will undergo three plasmapheresis sessions every 48 hours after receiving two doses of tocilizumab every 48 hours.

Main outcome variables
Blood oxygen level, clinical outcomes, frequency of recovery, serum levels of IL-6, white blood count, Ferritin, procalcitonin, CRP, D Dimer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220123053807N1**
Registration date: **2022-01-29, 1400/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-29, 1400/11/09**
Update count: **0**

Registration date
2022-01-29, 1400/11/09

Registrant information

Name
mohsen gholinataj jelodar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3312 2550

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-24, 1400/11/04

Expected recruitment end date
2022-02-23, 1400/12/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect tocilizumab, plasmapheresis and tocilizumab plasmapheresis combination in Coronavirus disease (COVID -19) patients admitted to the intensive care unit

Public title
The effect of tocilizumab, plasmapheresis and tocilizumab plasmapheresis combination in COVID 19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with Coronavirus disease (COVID-19) admitted to intensive care units diagnosis of Covid-19 based on Polymerase chain reaction (PCR) of nasopharyngeal Serum C-reactive protein (CRP) and interleukin 6 levels are at least twice normal Oxygen saturation (o2sat) more than 80% without supplemental oxygen or Respiratory Rate (RR) more than 24

Exclusion criteria:
History of drug allergy Platelets less than 50000 Suspected by active viral (Non-COVID), bacterial and fungal infections Primary intubation absolute neutrophil count (ANC) less than 500 Any clinical suspicion of gastrointestinal obstruction Pregnancy and lactation Patient or family dissatisfaction

Age
From **18 years** old to **68 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The data collector will not know the type of intervention. Also, the data analyzer will not know the type of intervention. The study will be conducted blindly.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Yazd Shahid Rahnemon Hospital

Street address
Shahid Rahnemon Hospital, Farokhi Ave., Yazd Town

City
Yazd

Province
Yazd

Postal code
8913814396

Approval date
2022-01-04, 1400/10/14

Ethics committee reference number
IR.SSU.SRH.REC.1400.023

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
mortality

Timepoint
daily until discharge

Method of measurement
medical record

2

Description
need for mechanical ventilation

Timepoint
daily until discharge

Method of measurement
medical record

3

Description
oxygenation rate

Timepoint
daily until discharge

Method of measurement
medical record

Secondary outcomes

1

Description
Number of days hospitalized in the intensive care unit
Timepoint
Daily until discharge
Method of measurement
medical record

2

Description
Duration of hospitalization
Timepoint
Daily until discharge
Method of measurement
medical record

3

Description
Inflammatory biomarkers (ferritin, LDH, IL6, CRP)
Timepoint
Before and after all interventions
Method of measurement
ELIZA technique

Intervention groups

1

Description
Intervention group 1: Patients in the tocilizumab group will receive two doses of 400 mg of tocilizumab(temziva, AryoGen Pharmed) every 24 hours.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients of plasmapheresis group undergo three sessions of plasmapheresis every 48 hours by centrifugation method with fresh frozen plasma (FFP)
Category
Treatment - Other

3

Description
Intervention group 3: Patients in the tocilizumab and plasmapheresis groups will undergo three plasmapheresis sessions every 48 hours after receiving two doses of tocilizumab (temziva, AryoGen Pharmed)every 48 hours.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Teaching Hospitals of Yazd University of Medical Sciences
Full name of responsible person
Mohsen Gholinataj Jelodari
Street address
Farokhi ave., Yazd town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Vice Chancellor of Research, Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences, Bahonar Square
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dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mohsen Gholinataj Jelodar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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
"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