# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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
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rahnamoon@ssu.ac.ir

## 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**
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## Person responsible for scientific inquiries

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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