Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy and safety of tofacitinib on clinical improvement in hospitalized patients with COVID19: A randomized, double blind multi-centre clinical trial

Protocol summary

Study aim
Efficacy of tofacitinib in hospitalized patients with COVID-19

Design
Patients are nominated for tofacitinib or placebo for two weeks or until hospitalization according to the randomization table by permuted block method in 4 blocks. The dose of tofacitinib received is 10 mg twice daily and in the control group received placebo with the same shape and color as tofacitinib and similar frequency . All patients admitted to the study receive a standard treatment regimen.

Settings and conduct
Patients referred to Medical Center of Ibn Sina Sari, Imam Khomeini Tehran University of Medical Sciences and Imam Hossein Shahid Beheshti University of Medical Sciences of Tehran with a diagnosis of COVID-19 who need for hospitalization and study inclusion criteria were divided into two groups according to the randomization table. all patient were evaluated during hospitalization and up to 28 days. The physician, patient, and evaluator are unaware of the type of medication intervention.

Participants/Inclusion and exclusion criteria
Adult patients over 18 years of age admitted to the hospital with a diagnosis of Covid-19 based on clinical findings and results of pulmonary CT-scan and who have developed symptoms of Covid-19 in the last two weeks are included in the study. Hospitalization criteria include saturated oxygen content less than 94%. Pregnant and lactating women, severe hepatic impairment (Child-pugh C) or increase in liver enzymes more than 3 times normal, renal failure (glomerular filtration less than 30 ml / min), chronic use of immunosuppressive drugs or corticosteroids, absolute lymphocyte count less Out of 500 per cubic millimeter, absolute neutrophil counts less than 1000 per cubic millimeter were excluded from the study.

Intervention groups
Prescribing tofacitinib

Main outcome variables
Improving the clinical symptoms of patients with Covid-19

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190804044429N7**
Registration date: **2021-10-27, 1400/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-27, 1400/08/05**
Update count: **0**

Registration date
2021-10-27, 1400/08/05

Registrant information

Name
Monireh Ghazaeian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8863 6864

Email address
ghazaeianm@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-22, 1400/07/30

Expected recruitment end date
2022-01-20, 1400/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and safety of tofacitinib on clinical improvement in hospitalized patients with COVID19: A randomized, double blind multi-centre clinical trial

Public title
Efficacy and safety of tofacitinib on clinical improvement in patients with COVID19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalization with oxygen saturation less than 94% COVID-19 diagnosis according to chest CT scan or RT-PCR
Exclusion criteria:
Pregnancy lactating women Severe liver failure (Child-pugh C) or liver enzymes more than 3 times normal Renal failure (glomerular filtration less than 30 ml / min) Chronic use of immunosuppressive drugs or corticosteroids Absolute lymphocyte count less than 500 per cubic millimeter Absolute neutrophil counts less than 1000 per cubic millimeter
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are eligible for tofacitinib or placebo for one weeks or until hospitalization according to the randomized table by permuted block in blocks 4.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind. Outcome elevator and participant are blinded (double blind) and aware from grouping (intervention or placebo).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences
Street address
Ibn Sina Hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4816864193
Approval date
2021-09-29, 1400/07/07
Ethics committee reference number
IR.MAZUMS.REC.1400.456

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
U07.1
ICD-10 code description
Covid-19 disease

Primary outcomes

1

Description
Improving the clinical symptoms of patients with covid-19
Timepoint
Day one, day seven, day 14, day 28
Method of measurement
eight-category ordinal scale

Secondary outcomes

1

Description
Mortality rate
Timepoint
During hospitalization and on days 14 and 28
Method of measurement
Observation

2

Description
Admission in intensive care units

Timepoint
During hospitalization
Method of measurement
Observation

3

Description
Ventilator need
Timepoint
During hospitalization
Method of measurement
Observation

4

Description
Incidence of possible side effects
Timepoint
During hospitalization
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: all the patients received remdesivir (200 mg on the first day followed by 100 mg daily for five days and, corticosteroid therapy (Dexamethasone 8 mg or equivalent dose of other corticosteroid) , DVT prophylaxis and tofacitinib tablet (Zistdaru Daneshcompany)10 mg twice daily for seven days or until hospitalization.
Category
Treatment - Drugs

2

Description
Control group: all the patients received remdesivir (200 mg on the first day followed by 100 mg daily for five days and, corticosteroid therapy (Dexamethasone 8 mg or equivalent dose of other corticosteroid) , DVT prophylaxis and placebo tablet (Zistdaru Daneshcompany) twice daily for seven days or until hospitalization.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina hospital
Full name of responsible person
Monireh Ghazaeian
Street address
Ibn Sina hospital, Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3334 3011
Email
ghazaeianm@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
Street address
Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way , Sari, Iran.
City
Sari
Province
Mazandaran
Postal code
48157-33971
Phone
+98 11 3448 4800
Fax
+98 11 3335 2725
Email
majsaeedi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Monireh Ghazaeian
Position

Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province, Iran.

City
Sari

Province
Mazandaran

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4815733971

Phone
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ghazaeianm@gmail.com

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data related to the initial outcomes of the study will be shared

When the data will become available and for how long
The data will be available one year after publication

To whom data/document is available
Academic researchers, medical team and scientific institutes

Under which criteria data/document could be used
Requests for sharing data should be sent to the person responsible for general inquiries

From where data/document is obtainable
Requests for sharing data should be sent to the person responsible for general inquiries. ghazaeianm@gmail.com

What processes are involved for a request to access data/document
Person in charge of scientific study will reply to the request within 10 days. khalilih@tums.ac.ir

Comments