Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

A comparative study of the effects of Tocilizumab, interferon-gamma and vitamin C on the recovery of critically ill Covid-19 patients and cytokine storm

Protocol summary

Study aim
Effects of Tocilizumab, interferon-gamma and vitamin C on serum ferritin, LDH, CPK, CRP lung tissue, heart, lymphocytes, neutrophils, PCO2, and serological tests.

Design
The randomized clinical trial consists of a control group,two parallel groups,non blinded,and phase 2. All the 60 patients are systematically assigned to random groups. Randomization will be conducted by SAS software.

Settings and conduct
This clinical trial will be undertaken at Ahar Hospital, in East Azarbaijan Province, Iran, under the supervision of Tabriz University of Medical Sciences. It is approved by the ethics committee of TUOMS. In all patients, the serum levels of ferritin, LDH, CPK,CRP,IL1,IL6,IL18,TNFa should be significantly higher, and pulmonary involvement should be evident in the CT scan. In addition to the routine medication, Group 1 will receive the Tocilizumab Vial. Group 2 will receive interferon-gamma and Vitamin C besides the usual medication, and the control group will receive only the routine medication. All patients will be monitored for two weeks. In the first and last days of treatment, a CT scan will be performed for patients to examine the lungs and heart. Blood samples will also be taken to check blood constituents (neutrophils, lymphocytes, ferritin, ALT, AST, VBG). In the next step, PCO2 will be measured. All of the above steps will be repeated on days 3-7-10, and 14.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Lack of a specific clinical disease, 18 to 65 years of age, no pregnancy, symptoms of cytokine storm, Exclusion criteria: An underlying illness, under 18 and over 65 years of age, pregnancy

Intervention groups
1: Tocilizumab along with routine medications, 2: interferon-gamma and Injectable vitamin C along with routine medications, 3: Only routine medications

Main outcome variables
Ferritin serum LDH CPK CRP IL1,IL6,IL18,TNFa

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200525047570N1**
Registration date: **2020-07-30, 1399/05/09**
Registration timing: **prospective**

Last update: **2020-07-30, 1399/05/09**
Update count: **0**

Registration date
2020-07-30, 1399/05/09

Registrant information

Name
Negin Hadisi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 4432 6311

Email address
nhadisi72@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-31, 1399/05/10

Expected recruitment end date
2020-08-07, 1399/05/17

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effects of Tocilizumab, interferon-gamma and vitamin C on the recovery of critically ill Covid-19 patients and cytokine storm

Public title
A comparative study of the effects of Tocilizumab, interferon-gamma and vitamin C on the recovery of critically ill Covid-19 patients and cytokine storm
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Lack of a specific clinical disease Non-use of a particular drug No pregnancy
Exclusion criteria:
A specific clinical disease Taking a particular drug Pregnancy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Considering the budget allocated by Tabriz University of Medical Sciences and the relatively low number of acute patients in Baqer al-Olum Hospital in Ahar, we will use the "simple randomizasion method, the ratio of 1:1, in this study, and the SAS statistical software is utilized as the randomization tool.
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 in Research, Tabriz University of Medical Sciences
Street address
Jangdoost Alley,Vahdat Street, Next to the Pouri Post Bank, Naser Hadisi
City
Sardasht
Province
West Azarbaijan
Postal code
5961658164
Approval date
2020-05-18, 1399/02/29
Ethics committee reference number
IR.TBZMED.REC.1399.130

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
Blood ferritin levels
Timepoint
Days 1-3-7-10-14
Method of measurement
ELISA kit

2

Description
Blood C-reactive protein levels
Timepoint
Days 1-3-7-10-14
Method of measurement
ELISA kit

3

Description
Blood creatine Phosphokinase levels
Timepoint
Days 1-3-7-10-14
Method of measurement
ELISA kit

4

Description
Low-density lipoprotein levels
Timepoint
Days 1-3-7-10-14
Method of measurement

ELISA kit

5

Description
Lung tissue
Timepoint
Days 1 and 14
Method of measurement
Computed tomography CT-scan

6

Description
Blood Lymphocyte levels
Timepoint
Days 1-3-7-10-14
Method of measurement
ELISA kit

7

Description
Blood Neutrophil levels
Timepoint
Days 1-3-7-10-14
Method of measurement
ELISA kit

8

Description
Partial pressure of carbon dioxide (PCO2)
Timepoint
Days 1-3-7-10-14
Method of measurement
Arterial blood gas test

Secondary outcomes

1

Description
Tumor necrosis factor alpha, TNFa
Timepoint
Days 1, 3 ,7 , 14
Method of measurement
ELISA Kit

2

Description
Interleukin 1
Timepoint
Days 1 ,3 ,7 , 14
Method of measurement
ELISA Kit

3

Description
Interleukin 6
Timepoint
Days 1, 3, 7, 14
Method of measurement
ELISA Kit

4

Description
Interleukin 18
Timepoint
Days 1, 3, 7, 14
Method of measurement
ELISA Kit

Intervention groups

1

Description
Intervention Group 1 receives Tocilizumab Vial, a humanized antibody, and an interleukin 6 receptor. A dose of 162mg/0.9ml will be administered once a week Subconsciously for two weeks. Currently, no specific manufacturer has been chosen yet.
Category
Treatment - Drugs

2

Description
Intervention Group 2 receives Interferon gamma Vial, a humanized antibody, and an interleukin 12 receptor. A dose of 5mg/200mcg, subcutaneous, every alter day, and Vitamin C a dose of 500mg every 8h will be administered for one week. Currently, no specific manufacturer has been chosen yet.
Category
Treatment - Drugs

3

Description
Control group: : Only routine medications
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Bagher-Al-Olum Hospital of Ahar
Full name of responsible person
Negin Hadisi
Street address
Vahdat Street., Jangdoost Alley., Next to the Pouri Post Bank., Naser Hadisi
City
Sardasht
Province
West Azarbaijan
Postal code

5961658164

Phone
+98 44 4432 6311

Email
nhadisi72@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Hossein Somi

Street address
Vahdat Street,. Jangdoost Alley,. Next to the Pouri Post Bank,. Naser Hadisi

City
Sardasht

Province
West Azarbaijan

Postal code
5961658164

Phone
+98 44 4432 6311

Email
nhadisi72@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Negin Hadisi

Position
Student of the last term of Master of Anatomical Sciences

Latest degree
Master

Other areas of specialty/work
Midwife of women ward

Street address
Vahdat Street,. Jangdoost Alley,. Next to the Pouri Post Bank,. Naser Hadisi

City
Sardasht

Province
West Azarbaijan

Postal code
5961658164

Phone
+98 44 4432 6311

Email
nhadisi72@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Negin Hadisi

Position
Student of Master of Anatomical Sciences

Latest degree
Master

Other areas of specialty/work
Anatomy

Street address
Vahdat Street,. Jangdoost Alley,. Next to the Pouri Post Bank,. Naser Hadisi

City
Sardasht

Province
West Azarbaijan

Postal code
5961658164

Phone
+98 44 4432 6311

Email
nhadisi72@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Negin Hadisi

Position
Student of Master of Anatomical Sciences

Latest degree
Master

Other areas of specialty/work
Anatomy

Street address
Vahdat Street,. Jangdoost Alley,. Next to the Pouri Post Bank,. Naser Hadisi

City
Sardasht

Province
West Azarbaijan

Postal code

5961658164

Phone

004444326311

Email

nhadisi72@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

All the objectives and consequences of (All the data related) the participants' documents can be shared anonymously.

When the data will become available and for how long

The obtained data can be immediately accessed after samples are collected in the summer of 2020.

To whom data/document is available

Data and other documents can be sent to individuals working in academic and scientific institutions.

Under which criteria data/document could be used

Data can only be sent to individuals working in academic and scientific institutions, as well as physicians in the field of treatment.

From where data/document is obtainable

For more information , you can reach Negin Hadisi. Please send your request by a verified email to the following address: nhadisi72@yahoo.com

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

Please send your request by a verified email

Comments