Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of therapeutic effect of MAB98 including thymolic fraction of Trachyspermum ammi, thymoquinone fraction of Nigella sativa and colchicine of Colchicum autumnale in covid 19 patients

Protocol summary

Study aim
Evaluation of the therapeutic effect of MAB98 including thymolic fraction of Trachyspermum ammi, thymoquinone fraction of Nigella sativa and colchicine of Colchicum autumnale in COVID-19 patients

Design
This study is a randomized controlled unblinded trial. The control and intervention groups would be allocated by Block Randomization Method (each group: 60 cases).

Settings and conduct
This clinical trial would be performed in Golestan and Farabi hospitals in Kermanshah, Iran. The control group would receive only the standard treatment regime. The intervention group would received MAB98 (125 and 250 mg capsules 2 to 3 times daily for seven days) in addition to the standard treatment regime. This new formula containing colchicine that is extracted from colchicum autumnale using solvent extraction, thymoquinone and thymol that extracted from Nigella sativa and Trachyspermum ammi, respectively using hydro-alcoholic extraction and finally standardized against the active ingredients.

Participants/Inclusion and exclusion criteria
Inclusion criteria are finding(s) in favor of COVID-19 in Chest CT scan when accompanied with the clinical sign(s) and symptom(s) or RT-PCR-confirmed for COVID-19 in the sample of evaluated case. Signing the consent form by the person/legal guardian. Exclusion criteria are age lower than 10 years, pregnancy, and severe hepatic failure.

Intervention groups
60 inpatients with confirmed COVID-19 infection who have met inclusion and exclusion criteria which now receiving the standard treatment regime (Kaletra). These patients would receive MAB98 other than the standard treatment. The control group with 60 cases would receive the standard treatment (Kaletra) only.

Main outcome variables
The fatality rate, hospitalization duration, and need of intensive care unit administration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150623022884N3**
Registration date: **2020-11-18, 1399/08/28**
Registration timing: **retrospective**

Last update: **2020-11-18, 1399/08/28**
Update count: **0**

Registration date
2020-11-18, 1399/08/28

Registrant information

Name
Ali Mostafaie

Name of organization / entity
Medical Biology Research Center, Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 3427 9923

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amostafaie@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-08, 1399/01/20

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
2020-04-15, 1399/01/27
Actual recruitment end date
2020-05-19, 1399/02/30
Trial completion date
2020-06-14, 1399/03/25

Scientific title
Evaluation of therapeutic effect of MAB98 including thymolic fraction of Trachyspermum ammi, thymoquinone fraction of Nigella sativa and colchicine of Colchicum autumnale in covid 19 patients

Public title
MAB98 for treatment of Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chest CT scan/RT-PCR for Covid19 Clinical signs for Covid19
Exclusion criteria:
Age lower than 10 years pregnancy Sever hepatic disorder
Age
From **10 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted balanced block randomization method: In this study permuted balanced block randomization will used. It is recommended to use in small randomized control trials when we want treatment groups of equal sizes. In this permuted balanced block randomization, the blocked size is 4, the allocation ratio is 1 and number of intervention groups is 2. After specifying the block size, all the potential contribution of the assignments within each group must be calculated, and then the blocks are randomly chosen to determine the assignment of all participants. So, the total of sample size of participants randomized to two treatment groups, a randomized block method would be: block size is four, possible balance combinations with two intervention group I and two intervention group II in each block are calculated as 6 and where each block is randomly chosen to determine the assignment of all samples. Finally, 30 blocks with random permutation will be generated.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov
Secondary trial Id
NCT04392141
Registration date
2020-05-18, 1399/02/29

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Ccommittee of Kermanshah University of Medical Sciences
Street address
Building No 2, Kermanshah University of Medical Sciences, Shahid Beheshti boulevard
City
Kermanshah
Province
Kermanshah
Postal code
67148-69914
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.KUMS.REC.1399.062

Health conditions studied

1

Description of health condition studied
Coronavirus disease 2019 (COVID-19)
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Fatality rate
Timepoint
Since admission to 14th day after discharge
Method of measurement
Evaluation of vital signs (pulse rate and active ECG)

2

Description

Hospitalization duration

Timepoint

Since admission to discharge

Method of measurement

Days of hospitalization

Secondary outcomes

1

Description

Need of intensive care unit (ICU) admission

Timepoint

Admission to discharge

Method of measurement

This is a clinical judgment by the clinicians. In any case with unstable situation (such as ARDS) the patient must be admitted to ICU for a better care.

Intervention groups

1

Description

Intervention group: Patients diagnosed with COVID-19 who receiving the standard care including Kaletra or hydroxychloroquine, naproxen and other accessory drugs as well as MAB98 including 125 and 250 mgr capsules received 2 and 3 times daily, respectively for 6 (outpatients) or 12 days (inpatients). MAB98 consisting of extracted colchicine-rich fraction of Colchicum autumnale, as well as thymoquinone and thymol rich fractions of Nigella Sativa and Trachyspermum Ammi respectively which their effective components have been extracted through alcoholic and water extraction. MAB98 was manufacture in the Zist Tolid Razi Co.

Category

Treatment - Drugs

2

Description

Control group: Patients diagnosed with COVID-19 who receiving standard care including Kaletra or hydroxychloroquine, naproxen and other accessory drugs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Ali Mostafaie

Street address

Parastar Blvd

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2

Recruitment center

Name of recruitment center

22 Bahman health Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Shahid-Beheshti Blvd

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farid_n32@yahoo.com

Web page address

https://vc-research.kums.ac.ir/fa/moavenatt/moavenattahghi

Grant name

Grant code / Reference number

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

No

Title of funding source

Zist Tolid Razi Company

Proportion provided by this source

100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Ali Mostafaie

Position
Professor of Medical Immunology

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the possible miss-use of the data provided in this study as a sample group of COVID-19 patients in Kermanshah, the primary data of the patients would be kept confidential.

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Evaluated variables and collected data during the study would be available online after de-identification of participants' information.

When the data will become available and for how long
The online access for the data would be 12 months after publication of the results and any request before this embargo would be evaluated through the trial responsible person and acceptance of all team members.

To whom data/document is available

Any data from this trial would be available only for persons employed in Scientific and Academic organizations after receiving the team's permission.

Under which criteria data/document could be used

The accessed data that have been permitted to a third party (both legal or natural persons) is a reading only file and the team does not permit any further analysis on them unless permission has been provided.

From where data/document is obtainable

Dr. Ali Mostafaie amostafaie@kums.ac.ir Professor of Medical Immunology, Kermanshah University of Medical Sciences. 098-83-34279923

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

Firstly, a request and purpose of use should be submitted to Dr. Ali Mostafaie (emails are performed). Then after, he would discuss the issue with team members and you will be answered by email.

Comments