

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the effectiveness of thiamine-ascorbic acid-methylprednisolone (TAM) cocktail in the treatment of critically ill patients with coronavirus pneumonia (Covid-19) in a clinical trial study

Protocol summary

Study aim

Evaluation of the effectiveness of Thiamine-Ascorbic acid-Methylprednisolone (TAM) cocktail in the treatment of critically ill patients with Covid-induced pneumonia.

Design

Open-labeled, controlled, non-randomized, phase 2-3 clinical trial on 30 patients

Settings and conduct

Eligible patients who are admitted to the intensive care unit of Dr. Shariati Hospital not randomly will allocate to control or treatment group. During hospitalization outcomes will be assessed and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Agree to take an oropharyngeal PCR and venous blood sample according to the protocol, A non-pregnant man or woman 18 years of age or older entering the program , A positive covid 19 polymerase chain reaction test with at least one of the following: radiographic changes or with clinical signs requiring mechanical ventilation and Decreased blood oxygen equal or less than 94% in Room air, Women of childbearing age should have at least one method of contraception Exclusion criteria: Allergy to hydrocortisone or ascorbic acid or thiamine, Hospitalization less than 72 hour, Active kidney stones , The patient is in another pilot study at the same time.

Intervention groups

Intervention group: The patients will receive the cocktail contains 100 mg of Thiamine (Darou-Pakhsh) , 6 g Ascorbic acid (Darou-Pakhsh) and Methylprednisolone 250 mg (Pfizer) on the first day and then 100 mg of Thiamine and 6 gr of Ascorbic acid and 125 mg of Methylprednisolone on the second and third day of treatment. The cocktail will be prepared in 200 cc dextrose 5 % and slowly infused over 10 hours. Control group: Patients of this group will receive all of common treatments, except the cocktail composition.

Main outcome variables

changes in SF ratio; Time to mechanical ventilation weaning; Changes in Murray Score after 72 hours of enrollment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047080N2**

Registration date: **2020-11-07, 1399/08/17**

Registration timing: **retrospective**

Last update: **2020-11-07, 1399/08/17**

Update count: **0**

Registration date

2020-11-07, 1399/08/17

Registrant information

Name

Rasoul Aliannejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8490 2460

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2020-04-04, 1399/01/16

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of thiamine-ascorbic acid-methylprednisolone (TAM) cocktail in the treatment of critically ill patients with coronavirus pneumonia (Covid-19) in a clinical trial study

Public title
Evaluation of the effectiveness of TAC cocktail in critically ill patients with Covid 19 induced pneumonia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed written consent is obtained before the start of the study process. patient understands and agrees with planned study methods. Agree on sampling the oropharyngeal polymerase chain reaction and venous blood samples according to the protocol. A non-pregnant woman and man is 18 years of age or older when entering the program. Positive Covid 19 polymerase chain reaction test with at least one of the following: radio-graphic changes or with clinical signs requiring mechanical ventilation and air oxygen saturation level less than or equal to 94% in room air. Women of childbearing age should have at least one contraceptive method during the study
Exclusion criteria:
Allergic reaction to Hydrocortisone, Ascorbic acid or thiamine Hospitalization less than 72 hours Active kidney stone The patient participates in another clinical trial at the same time

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 of Tehran University of Medical Sciences

Street address

Tums central building ,Keshavarz boulevard,Tehran . Iran.

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2020-03-29, 1399/01/10

Ethics committee reference number

IR.TUMS.VCR.REC.1399.070

Health conditions studied

1

Description of health condition studied

Pneumonia induced with COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 pneumonia , virus identified

Primary outcomes

1

Description

Duration of improvement in the ratio of incoming oxygen flow to arterial oxygen pressure (SF ratio) compared to baseline

Timepoint

at baseline and daily

Method of measurement

Measurement of SPO2/FIO2 with pulse oximetry

2

Description

Time to mechanical ventilation weaning

Timepoint

Daily

Method of measurement

Counting the days of using ventilator

3

Description

Change in the Murray Lung Injury Score from baseline to 72 h

Timepoint

Baseline and daily to 72 h

Method of measurement

Murray Lung Injury Score

Secondary outcomes**1****Description**

Change in the Sequential Organ Failure Assessment (SOFA) score from baseline to 72 h

Timepoint

Baseline and daily to 72 h

Method of measurement

Measurement of SOFA score

2**Description**

Change in National Early Warning Score (NEWS) from baseline to discharge

Timepoint

Baseline and daily

Method of measurement

Measurement of NEWS score

Intervention groups**1****Description**

Intervention group: The patients will receive the cocktail contains 100 mg of Thiamine (Ampoule B complex, Darou Pakhsh Co.), 6 g Ascorbic acid (ampoule of vitamin C, Darou Pakhsh Co.) and Methylprednisolone 250 mg (Solu-Medrol, Pfizer Co.) on the first day and then 100 mg of Thiamine and 6 gr of Ascorbic acid and 125 mg of Methylprednisolone on the second and third day of treatment. The cocktail will be prepared in 200 cc dextrose 5 % and slowly infused over 10 hours.

Category

Treatment - Drugs

2**Description**

Control group: Patients of this group will receive all of common treatments (including medications and procedures), except the cocktail composition. During hospitalization outcomes will be assessed and medications and procedures will be recorded.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shariati Hospital

Full name of responsible person

Rasol Aliannejad

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Shariati Hospital, Jalal Al-Ahmad Highway, Tehran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad ali Sahraian

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Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd

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Web page address<https://vcr.tums.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Rasol Aliannejad

Position

Faculty

Latest degree

Subspecialist

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available