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)
Phone
+98 21 8490 2460
Email address
aliannejad@tums.ac.ir

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 oximetery

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
Street address
Shariati Hospital, Jalal Al-Ahmad Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad ali Sahraian
Street address
Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
141765376
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
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

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
aliannejad@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Rasoul Aliannejad

Position
Faculty

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Street address
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Tehran

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1411713135

Phone
+98 21 8490 1000

Email
aliannejad@tums.ac.ir

Person responsible for updating data

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

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8863 3039

Email
aliannejad@tums.ac.ir

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