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A study to assess the usefulness of combination of Vitamin D, magnesium and Vitamin B12 in older COVID-19 patients

Submission date
29/05/2020

Recruitment status
No longer recruiting

Registration date
01/06/2020

Overall study status
Completed

Last Edited
17/03/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The COVID-19 pandemic which began in late 2019 has raged across the globe with more than 4 million infections and 300,000 deaths recorded to date. A broad theme of immune overreaction has emerged as a key determinant of disease severity and patient outcome. Intuitively, immunomodulation becomes an attractive potential treatment strategy. Besides lung involvement, COVID-19 is a multi-organ phenomenon and appropriate systemic inflammatory control is necessary for overall survival benefit. Much of the current treatment effort is targeted at viral elimination instead of modulating immune overreaction. A number of immunomodulatory agents may be helpful including vitamin D, magnesium and vitamin B12. Importantly, these compounds are generally safe and well-tolerated by patients. A short course of these three supplements (DMB) could potentially exert synergistic effects to improve COVID-19 severity. This study aims to determine the usefulness of combination of vitamin D, magnesium and vitamin B12 in older COVID-19 patients.

Who can participate?
COVID-19-positive patients aged 50 and over

What does the study involve?
Patients will be given a combination of vitamin D, magnesium and vitamin B12, up to 14 days. The risk of clinical deterioration (requirement for supplemental oxygen and/or intensive care support) is measured using patient records from the hospital information system at day 30.

What are the possible benefits and risks of participating?
If proven to be effective, DMB could reduce the severity of COVID-19 in older patients. There is minimal risk since these supplements are generally safe and well-tolerated by patients.

Where is the study run from?
Singapore General Hospital (Singapore)

When is the study starting and how long is it expected to run for?
March 2020 to May 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Liam Pock Ho
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CIRB 2020/2344

Study information

Scientific Title
A cohort study to evaluate the effect of combination vitamin D, magnesium and vitamin B12 (DMB) on progression to severe outcome in older COVID-19 patients

Acronym

DMB

Study objectives
Does administering a combination of vitamin D, magnesium and vitamin B12 (DMB) to older COVID-19 patients reduce the severity of their infection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/05/2020, SingHealth institutional ethics committee (Singapore Health Services Pte Ltd, 31 Third Hospital Avenue, #03-03 Bowyer Block C, Singapore, 168753; +65(0) 6225 0488; irb@singhealth.com.sg), ref: 2020/2344

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Therapy comprised a single daily oral dose of vitamin D3 1000 IU, magnesium 150 mg and vitamin B12 500 mcg for up to 14 days, with follow-up to Day 30 from onset of symptoms.

Intervention Type
Supplement

Primary outcome measure
The risk of clinical deterioration, defined as the requirement for supplemental oxygen and/or intensive care support, measured using patient records from hospital information system at day 30

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
02/03/2020

Completion date
15/05/2020

Eligibility

Key inclusion criteria
All consecutive COVID-19-positive patients aged 50 years and above admitted to Singapore General Hospital during the study period

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
40 (20 untreated and 20 treated)

Total final enrolment
43

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
06/04/2020

Date of final enrolment
15/04/2020

Locations

Countries of recruitment
Singapore

Study participating centre
Singapore General Hospital
Outram Road
Singapore
Singapore
169608

Sponsor information

Organisation
SingHealth

Sponsor details
31 Third Hospital Avenue
#03-03 Bowyer Block C
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+65 (0)63237515
irb@singhealth.com.sg

Sponsor type
Hospital/treatment centre

Website
https://www.singhealth.com.sg/

ROR
https://ror.org/04me94w47

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
In the midst of preparation.

Intention to publish date
31/10/2020

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	17/03/2021	Yes	No