

COVID-19 Information



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The Study of Quadruple Therapy Zinc, Quercetin, Bromelain and Vitamin C on the Clinical Outcomes of Patients Infected With COVID-19

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government.  [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT04468139

[Recruitment Status](#) ⓘ : Recruiting

[First Posted](#) ⓘ : July 13, 2020

[Last Update Posted](#) ⓘ : July 13, 2020

See [Contacts and Locations](#)

Sponsor:

Ministry of Health, Saudi Arabia

Information provided by (Responsible Party):

[Study Details](#)

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Study Description

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Brief Summary:

There are currently no antiviral drugs with proven efficacy nor are there vaccines for its prevention. Unfortunately, the scientific community has little knowledge of the molecular details of SARS-CoV-2 infection. The drugs we are chosen are used as clinical trials for antiviral and there is no proven guide for specificity and effectiveness against the virus so the results are different Now the clinical trials and research authorities are work speedily to target the most proven treatment for the virus so anything is infantile until now. the covid-19 with time be more explained by scientists it is steroid response disease and cause thromosis and cytokine storm , the aim of the study to inhibit viral replication and decrease the severity of the disease as antiviral and anticytokine storm , antithrombosis Zinc is a mineral element needed to regulate adaptive immune cells' functions. Higher level of intracellular zinc showed to increase intracellular pH; which affect on RNA-dependent RNA polymerase and decrease replication mechanism of RNA viruses. Therefore, drugs that described as zinc ionophores could be used with zinc supplement to act as antiviral against many RNA viruses including SARS-CoV-2 Quercetin is natural compound act as zinc ionophore to cause zinc influx intracellular.

Quercetin is a safe natural anti-oxidant and anti-inflammatory polyphenolic compound that found in various natural sources include onion, red grapes, honey and citrus fruits. It was shown that quercetin has the ability to chelate zinc ions and act as zinc ionophore. Therefore, quercetin could have antiviral activity against many RNA viruses . Quercetin, a flavonoid found in fruits and vegetables, has unique biological properties that may improve mental/physical performance and reduce infection risk ; These properties form the basis for potential benefits to overall health and disease resistance, including anti-carcinogenic, anti-inflammatory, antiviral, antioxidant, and psychostimulant activities, as well as the ability to inhibit lipid peroxidation, platelet aggregation and capillary permeability, and to stimulate mitochondrial biogenesis .There are various studies that report the immunomodulatory effect of bromelain . Bromelain activates natural killer cells and augments the production of granulocyte-macrophage-colony stimulating factor, IL-2, IL-6 and decreases the activation of Thelper cells. Thus, bromelain decreases the majority of inflammatory mediators and has demonstrated a significant role as an anti-inflammatory agent in various conditions Vitamin C is known as an essential anti-oxidant.,and enzymatic co-factor for physiological reactions such as hormone production, collagen synthesis and immune potentiation . Naturally, an

insufficiency of vitamin C leads to severe injuries to multiple organs, especially to the heart and brain, since they are both highly aerobic organs that produce more oxygen radicals. In fact, studies of in vivo effect on vitamin C are difficult since most animals, except human and some primate, are capable of synthesizing vitamin C endogenously

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Covid-19	Drug: Quercetin Dietary Supplement: bromelain Drug: Zinc Drug: Vitamin C	Phase 4

Study Design

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[Study Type](#) ⓘ : Interventional (Clinical Trial)

Estimated [Enrollment](#) ⓘ : 60 participants

Allocation: N/A

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: The Study of Quadruple Therapy Zinc, Quercetin, Bromelain and Vitamin C on the Clinical Outcomes of Patients Infected With COVID-19

[Actual Study Start Date](#) ⓘ : June 20, 2020

Estimated [Primary Completion Date](#) ⓘ : July 20, 2020

Estimated [Study Completion Date](#) ⓘ : July 30, 2020

Resource links provided by the National Library of Medicine 



[MedlinePlus](#) related topics: [Vitamin C](#)

[Drug Information](#) available for: [Ascorbic acid](#) [Quercetin](#) [Sodium ascorbate](#)
[Zinc, elemental](#) [Magnesium ascorbate](#)


[U.S. FDA Resources](#)

Arms and Interventions

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Arm 	Intervention/treatment 
<p>Experimental: Quercetin</p> <p>Quercetin 500 g of quercetin Quercetin will be administered orally once daily, in the morning before breakfast for 5-10 days or patient improves or discharged</p>	<p>Drug: Quercetin</p> <p>Dietary Supplement: Quercetin Treatment a daily dose of quercetin (500 mg) will be taken orally by proven COVID-19 cases intervention</p> <p>Dietary Supplement: bromelain</p> <p>Dietary Supplement:Bromealin Treatment a daily dose of bromelain(500 mg) will be taken orally by proven COVID-19 cases intervention</p> <p>Drug: Zinc</p> <p>zinc 50 mg orally daily dose will be taken orally by proven COVID-19 cases intervention</p> <p>Drug: Vitamin C</p> <p>vitamin c 1000 mg orally daily by proven COVID-19 cases intervention</p>

Outcome Measures

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Primary Outcome Measures

1. days of stay at hospital after treatment and discharge [Time Frame: 28 days]
speed the days of recovery and discharge from hospital
2. serum zinc before and after treatment [Time Frame: 5-10 days]
the level of serum zinc is very important especially at chronic diseases

Secondary Outcome Measures

1. questionnaire including parameters like BMI,,smoking , underling diseases, immunological treatment , [Time Frame: 28 days]

according to questionnaire including BMI, smoking , underlying diseases like hypertension, diabetes , asthmatic , ..etc

2. day of negative conversion for nasopharyngeal swab for rt-PCR FOR covid-19
[Time Frame: 28 days]

day of negative conversion for nasopharyngeal swab for rt-PCR FOR covid-19

Eligibility Criteria

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Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies.](#)

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Age \geq 18 years
2. positive confirmed PCR covid-19
3. moderate to severe cases
4. obtained consent
5. must be able to swallow tablets

Exclusion Criteria:

1. Patients who live outside Saudia Arabia
2. Pregnant women: Current known pregnancy positive pregnancy test.
3. Lactating women.

4. Documented allergy to pineapple or to quercetin

5. Documented history of mental illnesses

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT04468139

Contacts

Contact: amr ahmed 00966597310032 drmedahmed@gmail.com

Contact: abdullah Alqattan 00966540745588 abdullahalkattan@gmail.com

Locations

Saudi Arabia

Ministry of health.First health cluster ,Riyadh

Recruiting

Riyadh, Saudi Arabia

Contact: yousef albalawi 00966542460550 dryousef37@gmail.com

Sponsors and Collaborators

Ministry of Health, Saudi Arabia

Investigators

Study Director: Hiba Hamadelnil elsaeed Netherlands: Ministry of Health, Welfare and Sports

More Information

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Responsible Party: Amr kamel khalil Ahmed, director of mobile team tuberculosis ghubera, tuberculosis control program, Ministry of Health, Saudi Arabia

ClinicalTrials.gov Identifier: [NCT04468139](https://clinicaltrials.gov/ct2/show/study/NCT04468139) [History of Changes](#)

Other Study ID Numbers: 20-95M

First Posted: July 13, 2020 [Key Record Dates](#)

Last Update Posted: July 13, 2020

Last Verified: July 2020

Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Product Manufactured in and Exported from the U.S.: Yes

Additional relevant MeSH terms:

Ascorbic Acid

Growth Substances

Quercetin

Physiological Effects of Drugs

Vitamins

Antioxidants

Micronutrients

Molecular Mechanisms of Pharmacological Action

Nutrients

Protective Agents