**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: June 5, 2020

**ClinicalTrials.gov ID: NCT04421391**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | QuadraMune002 |
| Brief Title: | QuadraMune(TM) for Prevention of COVID-19 |
| Official Title: | Phase II Study of QuadraMune(TM) for Prevention of COVID-19 in High Risk Populations |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | June 2020 |
| Overall Status: | Recruiting |
| Study Start: | June 8, 2020 [Anticipated] |
| Primary Completion: | November 1, 2020 [Anticipated] |
| Study Completion: | November 8, 2020 [Anticipated] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Therapeutic Solutions International |
| Responsible Party: | Sponsor |
| Collaborators: | |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | No |
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: 57689<br>Board Name: La Jolla IRB<br>Board Affiliation: La Jolla IRB is an independent IRB<br>Phone: 3104285196<br>Email: littlekalina@gmail.com<br>Address:<br><br>7840 Stalmer St<br>#B6, San Diego, CA 92111 |
| Data Monitoring: | No |

| | |
|---|---|
| FDA Regulated Intervention: | No |

## Study Description

**Brief Summary:** QuadraMune(TM) is a nutritional supplement which has previously been demonstrated to possess antiinflammatory and immune modulatory activity based on in vitro and pilot in vivo studies. The current clinical trial aims to assess in a 500 volunteer trial the efficacy of QuadraMune(TM) in reducing infection in individuals at high risk of COVID-19.

**Detailed Description:** QuadraMune(TM) is composed of 4 natural ingredients.

Pterostilbene is an analogue of resveratrol, and has been shown to possess antiinflammatory activity. Additionally, this compound suppresses macrophage activation while enhancing NK activity.

Epigallocatechin gallate (EGCG) is one of the active ingredients in green tea and has been shown to act as an activator of T cells, and a suppressor of neutrophil mediated inflammation.

Sulforaphane is derived from broccoli and studies have shown that it protects lungs from inflammatory pathology.

Thymoquinone, which is chemically related to hydroxychloroquine, possessing antiviral effects and increases NK activity.

QuadraMune is a combination of these ingredients and is believed to possess superior in vitro and in vivo therapeutic properties as compared to when the ingredients are administered individually.

The study aims to assess preventative effects of QuadraMune(TM) administration for 12 weeks.

## Conditions

**Conditions:** Covid19
Coronavirus
SARS-CoV 2

**Keywords:** Immunology
Innate Immune System

## Study Design

| | |
|---|---|
| Study Type: | Interventional |
| Primary Purpose: | Treatment |
| Study Phase: | N/A |
| Interventional Study Model: | Single Group Assignment |
| Number of Arms: | 1 |
| Masking: | None (Open Label) |
| Allocation: | N/A |
| Enrollment: | 500 [Anticipated] |

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Treatment Arm<br>Patients will receive 2 pills of QuadraMune(TM) daily for 12 weeks | Dietary Supplement: QuadraMune(TM)<br>QuadraMune(TM) is a commercially available nutritional supplement |

## Outcome Measures

Primary Outcome Measure:

1. Prevention of COVID-19
   Prevention of COVID-19 symptoms as recorded in a daily diary

   [Time Frame: 12 Weeks]

Secondary Outcome Measure:

2. Safety as determined by presence or absence of Adverse Events and Serious Adverse Events
   Assessment of adverse events and serious adverse events will be performed.

   [Time Frame: 12 Weeks]

## Eligibility

Minimum Age: 18 Years

Maximum Age: 120 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- Informed consent, provided electronically via the EDC, demonstrating the subject understands the procedures required for the study and the purpose of the study Male or female patients 18 years of age or older that are considered to be high-risk individuals.
- High-risk individuals are defined as all health care workers in hospitals, clinics, and emergency rooms, and medical facilities.
- Subjects must agree to practice at least two highly effective methods of birth control for the duration of the study This includes condoms with spermicide, oral birth control pills, contraceptive implants, intra-uterine devices, or diaphragms. At least one of these must be a barrier method. Subjects not of reproductive potential will be exempt (e.g. post-menopausal, surgically sterilized)

Exclusion Criteria:

- Refusal to provide informed consent Any previous positive test for COVID-19 by RT-PCR Symptomatic for COVID-19 Diarrhea prior to the start of treatment Type I or II diabetes Atherosclerotic Coronary Artery Disease

Any contraindication for treatment with hydroxychloroquine including:

Hypoglycemia G6PD deficiency Porphyria Anemia Neutropenia Alcoholism Myasthenia Gravis Skeletal muscle disorder Maculopathy Changes in the visual field Liver disease, with ALT/AST > 2.5 upper limit normal and total bilirubin

>2.5 upper limit normal Psoriasis Any comorbidities which, in the opinion of the investigator, constitute health risk for the subject.

## Contacts/Locations

Central Contact Person: Thomas E Ichim, Ph.D
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Central Contact Backup:

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Therapeutic Solutions International

Locations: **United States, California**
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## IPDSharing

Plan to Share IPD: Undecided

## References

Citations:

Links:

Available IPD/Information: