COVID-19 and TCM: An Update on the FDA-Approved Clinical Studies

John K. Chen, Ph.D., Pharm.D., O.M.D., L.Ac.

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COVID-19 and TCM: An Update on the FDA-Approved Clinical Studies

- Several major colleges and medical schools are conducting research on COVID-19 and TCM.
  - UCLA (University of California Los Angeles) and UCSD (University of California San Diego)
  - USC (University of Southern California)
  - SIEAM (Seattle Institute of East Asian Medicine)
  - Others

- Disclaimer: This course only refers to the research aspect and currently there are no ‘proven’ treatments for COVID-19’.

University of California | Centers for Integrative Medicine & Health

are conducting a clinical trial of an

Herbal Formula for COVID-19

If you recently tested positive for COVID-19, you might qualify* to participate

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- ✓ **Earn $250 for completing the study!**
- ✓ **Your health will be monitored during this period and at two follow-up calls afterward.**
- ✓ **No clinic visits are required.**
- ✓ **The study will take place from the comfort of your home!**

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*To qualify for participation in this study, you will need to meet the following eligibility criteria:

1. Positive COVID-19 diagnosis
2. Age 18 or older
3. Avoid alcohol, cannabis and dairy during the 14 days of the treatment
4. Must not be pregnant or become pregnant during 14 days of the treatment and for 14 days after

This study is intended for persons sick with COVID-19. If you join the study, you'll be asked to take study formula at home daily for 14 days.

If you are interested in this study, and would like further details, please contact the Study Coordinator at **858-249-6896** or via email: covid19trial@ucsd.edu

UNIVERSITY OF CALIFORNIA UC Health

UNIVERSITY OF CALIFORNIA UC Health

University of California | Centers for Integrative Medicine & Health

- Multicenter Double Blind, Placebo Controlled RCT of Modified *Qing Fei Pai Du Tang* (mQFPD) for COVID-19

UCLA

UC San Diego

Brief Summary

- This is a multi-center, randomized, double-blind, placebo-controlled clinical trial to evaluate a 21-herb formula named modified Qing Fei Pai Du Tang (mQFPD) to treat COVID-19-positive outpatients with mild-tomoderate symptoms assigned to self-quarantined and home management. This the study aims to establish the safety and feasibility of the use of mQFPD vs placebo in 66 total subjects. Subsequent trials will evaluate other therapeutics as well as the efficacy of mQFPD in a larger study population

Detailed Description

- Study participants will be assigned to one of two groups, either placebo or mQFPD. Participants will be screened and consented remotely. Both groups will receive blood draws at days 1 and 14, and will be sent study medication directly to their home from the investigational pharmacy. Baseline and endof-study laboratory draws will be done at home via mobile phlebotomy. Adverse events and symptoms scores will be monitored by entry into a daily diary along with regular phone calls with the study coordinators. At the end of the study, safety will be assessed by laboratory measures and adverse event reporting

Study Design

Condition or disease	Intervention/treatment	Phase
Covid19	Drug: mQFPD Drug: organic brown rice	Phase 1

https://clinicaltrials.ucbraid.org/trial/NCT04939415
https://clinicaltrials.gov/ct2/show/NCT04939415

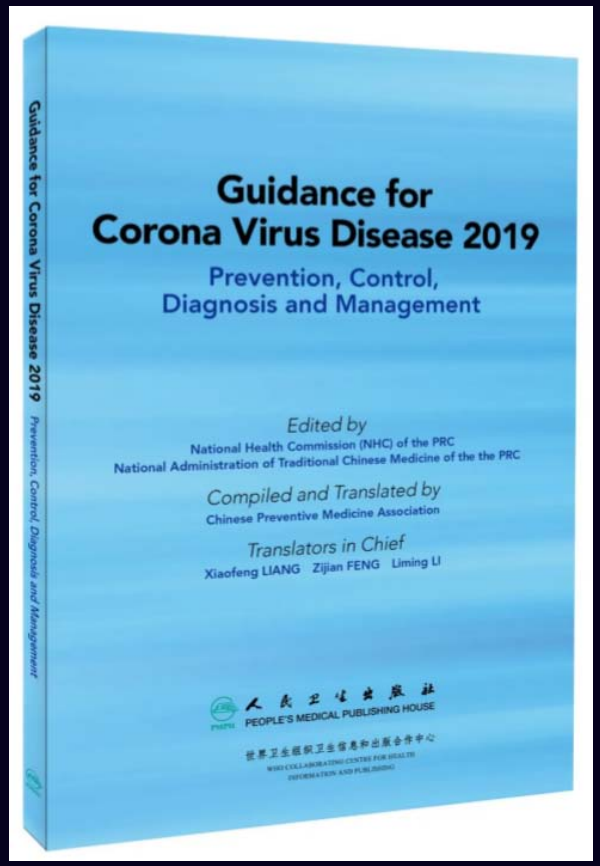
Study Design

Study Design Go to

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	66 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Triple (Participant, Care Provider, Investigator)
Primary Purpose:	Treatment
Official Title:	Multicenter Double Blind, Placebo Controlled RCT of Modified Qing Fei Pai Du Tang (mQFPD) for COVID-19
Actual Study Start Date :	July 1, 2021
Estimated Primary Completion Date :	July 1, 2022
Estimated Study Completion Date :	December 31, 2022

https://clinicaltrials.ucbraid.org/trial/NCT04939415
https://clinicaltrials.gov/ct2/show/NCT04939415

Guidance for Corona Virus Disease 2019



- Chinese version
  - 7th edition
  - 8th edition
- English version

英文版全文 _ 新型冠状病毒肺炎防控和诊疗指南
https://mp.weixin.qq.com/s/nOAmosQ4YqkXHKdJbBE9GA

Guidance for Corona Virus Disease 2019

- Medical Observation Period: Type 1 and Type 2
- Clinical Treatment Period (for confirmed cases)
  - General Type
  - Mild Type:
    - Cold dampness stagnating Lungs
    - Damp heat accumulated Lungs
  - Moderate Type:
    - Damp poison stagnating Lungs
    - Cold dampness obstructing Lungs
  - Severe Type:
    - Lung blocked by epidemic toxin
    - Flaring heat in Qi and Ying levels
  - Critical Type:
    - Internal block and outward desertion
- Recovery Period:
    - Lung and Spleen qi deficiency
    - Deficiency of qi and yin

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https://mp.weixin.qq.com/s/nOAmosQ4YqkXHKdJbBE9GA

清肺排毒汤 *Qing Fei Pai Du Tang* (Lung Cleansing & Detoxifying Decoction)

- 麻黄杏仁甘草石膏湯 *Má Huáng Xìng Rén Gān Cǎo Shí Gāo Tāng* (Ephedra, Apricot Kernel, Licorice, and Gypsum Decoction)
- 射干麻黃湯 *Shè Gān Má Huáng Tāng* (Belamcanda and Ephedra Decoction)
- 小柴胡湯 *Xiǎo Chái Hú Tāng* (Minor Bupleurum Decoction)
- 五苓散 *Wǔ Líng Sǎn* (Five-Ingredient Powder with Poria)

清肺排毒汤 *Qing Fei Pai Du Tang* (Lung Cleansing & Detoxifying Decoction)

- *Ma Huang* (Herba Ephedrae), 9g
- *Zhi Gan Cao* (Radix et Rhizoma Glycyrrhizae Praeparata cum Melle), 6g
- *Ku Xing Ren* (Semen Armeniacae Amarum), 9g
- *Shi Gao* (Gypsum Fibrosum), 15-30g (pre-decoct)
- *Gui Zhi* (Ramulus Cinnamomi), 9g
- *Ze Xie* (Rhizoma Alismatis), 9g
- *Zhu Ling* (Polyporus), 9g
- *Bai Zhu* (Rhizoma Atractylodis Macrocephalae), 9g
- *Fu Ling* (Poria), 15g
- *Chai Hu* (Radix Bupleuri), 16g
- *Huang Qin* (Radix Scutellariae), 6g
- *Jiang Ban Xia* (Rhizoma Pinelliae Praeparatum cum Zingibere et Alumine), 9g
- *Sheng Jiang* (Rhizoma Zingiberis Recens), 9g
- *Zi Wan* (Radix et Rhizoma Asteris), 9g
- *Kuan Dong Hua* (Flos Farfarae), 9g
- *She Gan* (Rhizoma Belamcandae), 9g
- *Xi Xin* (Radix et Rhizoma Asari), 6g
- *Shan Yao* (Rhizoma Dioscoreae), 12g
- *Zhi Shi* (Fructus Aurantii Immaturus), 6g
- *Chen Pi* (Pericarpium Citri Reticulatae), 6g
- *Guang Huo Xiang* (Herba Pogostemonis), 9g

清肺排毒汤 *Qing Fei Pai Du Tang* (Lung Cleansing & Detoxifying Decoction)

- 麻黄 *Má Huáng* (Herba Ephedrae) contains ephedrine alkaloids and the use may be restricted or prohibited. Substitution options include *Xiang Ru* (Herba Moslae), *Di Long* (Pheretima), *Ku Xing Ren* (Semen Armeniacae Amarum) and *Zi Su Zi* (Fructus Perillae).
- 款冬花 *Kuǎn Dōng Huā* (Flos Farfarae) contains pyrrolizidine alkaloids and the use may be restricted or prohibited. Substitution options include *Ku Xing Ren* (Semen Armeniacae Amarum), *Zi Wan* (Radix et Rhizoma Asteris), *Zi Su Zi* (Fructus Perillae) or *Pi Pa Ye* (Folium Eriobotryae).
- 細辛 *Xì Xīn* (Radix et Rhizoma Asari) contains aristolochic acid and the use may be restricted or prohibited. Substitution options include *Qiang Huo* (Rhizoma et Radix Notopterygii), *Fang Feng* (Radix Saposhnikoviae), *Gan Jiang* (Rhizoma Zingiberis) or *Jie Zi* (Semen Sinapis).

Drug: mQFPD or Placebo

- The dosage of mQFPD or placebo is 8 capsules three times a day for 14 consecutive days. It does not need to be consumed with food. It is best taken at least 30 minutes before OR at least 60 minutes after meals, in the morning, noon and evening. Accidentally missed doses will not need to be taken at a later time but will be recorded in a daily diary.

https://clinicaltrials.ucbraid.org/trial/NCT04939415
https://clinicaltrials.gov/ct2/show/NCT04939415

mQFPD

Primary Outcome Measures

1. Incidence of Treatment-Emergent Adverse Events [Safety and Tolerability] [Time Frame: 2 months] Quantitative monitoring of SARS-CoV-2 shedding in order to detect early potential increases in SARS-CoV-2 viral load during treatment. The safety of the study medication will also be assessed through laboratory data collection at baseline, and at either the end of the treatments
2. Feasibility of the intervention [Time Frame: 2 months] With the primary outcomes focusing on determination of the rates of recruitment and completion

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Secondary Outcome Measures:

1. Duration of viral illness
2. Hospitalization rate
3. ICU admission rate
4. Ventilatory requirement
5. Lymphocyte count
6. Neutrophil count
7. Ferritin
8. D-dimer
9. Lactate dehydrogenase
10. C-reactive protein
11. Troponin
12. Mid-turbinate SARS CoV-2 viral load

https://clinicaltrials.ucbraid.org/trial/NCT04939415
https://clinicaltrials.gov/ct2/show/NCT04939415

Other

- Inclusion Criteria
- Exclusion Criteria

https://clinicaltrials.ucbraid.org/trial/NCT04939415
https://clinicaltrials.gov/ct2/show/NCT04939415

More Information

- Responsible Party: Gordon Saxe M.D., Director, Krupp Center for Integrative Research, University of California, San Diego
- ClinicalTrials.gov Identifier: NCT04939415 History of Changes
- Other Study ID Numbers: 200633-1b

https://clinicaltrials.ucbraid.org/trial/NCT04939415
https://clinicaltrials.gov/ct2/show/NCT04939415

Indepth Webinars

- https://www.elotus.org/free-course/clinical-study-ucla-ucsd
- https://www.pacificcollege.edu/news/blog/2021/09/15/groundbreaking-fda-approved-study-mushrooms-and-chinese-herbs-for-covid-19

PILOT XFBD IN COVID-19

A Randomized, Double-Blind, Placebo-Control Pilot Trial of Xuanfei Baidu Granules (XFBD), a Traditional Chinese Medicine (TCM), in Persons with COVID-19:
FDA IND-150945, IRB HS-20-00632

The purpose of this study is to document the safety of taking traditional Chinese medicine (TCM) in patients with COVID-19 and to gain information to determine whether a study with TCM can be conducted. The study will test a traditional Chinese medicine that has been made into a granule formulation called Xuanfei Baidu Granules.

For more information contact: xfbd-info-l@mymaillists.usc.edu or call (818) 309 – 5542

USC Michelson Center

- A Randomized, Double-Blind, Placebo-Control Pilot Trial of Xuanfei Baidu Granules (XFBD), a Traditional Chinese Medicine (TCM), in Persons With COVID-19

Brief Summary

- The purpose of this study is to document the safety of taking traditional Chinese medicine (TCM) in patients with COVID-19 and to gain information to determine whether a study with TCM can be conducted. The study will test a traditional Chinese medicine that has been made into a granule formulation called Xuanfei Baidu Granules.

Detailed Description

- Xuanfei Baidu granules (XFBD) is a 13 medicinal traditional Chinese medicine (TCM) prescription developed by Dr. Zhang Boli, a member of Chinese Academy of Engineering, and his team, and used in Wuhan, China, during the initial outbreak of SARS-CoV2. Based on TCM theory, the 13 medicinals used mainly consist of heat-clearing and toxin-removing medicinals to reduce fever and clear viruses; cough-suppressing and phlegm-transforming medicinals to thin and clear the phlegm; and lung-diffusing and pant-calming to soothe the tracheal smooth muscle and relieve shortness of breath. Another unique quality is one of the medicinals helps to dissipate stasis and dissolves blood clots, providing a mild anticoagulant effect.

Detailed Description

- Before the widespread usage of TCM, nationwide China saw a progression of disease of about 10% of their mild and moderate cases while during the period with the TCM utilization, the percentage dropped to 2-5% depending on the hospital. Overall, they saw an improvement of clinical symptoms. Due to the challenges of the rapidly evolving outbreak, these are clinical observations and not evidence from a controlled study.

https://clinicaltrials.gov/ct2/show/NCT04810689

Detailed Description

- The purpose of this initial pilot study is to document the safety of taking a TCM in patients with COVID-19 and to gain information to determine whether a study with TCM can be conducted in the US. The study will test a TCM which has been made into a granule formulation called XFBD.

Detailed Description

- This is a randomized double-blind placebo-control pilot trial to document safety and efficacy endpoint assessments and to determine the feasibility of community recruitment and enrollment of symptomatic adult outpatients with COVID-19. The 12-week pilot will have 14 days where they receive XFBD or a placebo, orally twice a day and a 10 week follow up. The study will have a total of 60 participants with approximately 30 participants in each treatment arm. The participants will be randomized 1:1 individuals.

https://clinicaltrials.gov/ct2/show/NCT04810689

Study Design

Condition or disease	Intervention/treatment	Phase
Covid19	Drug: Xuanfei Baidu Granules Other: Placebo	Phase 2

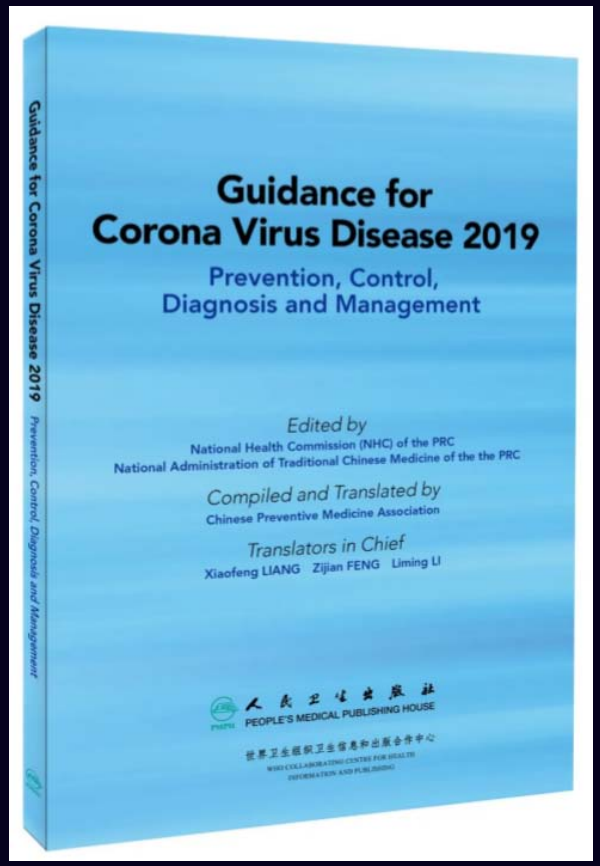
https://clinicaltrials.gov/ct2/show/NCT04810689

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	60 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Study participants will be randomized to 1 of 2 arms: XFBD granules or placebo
Masking:	Triple (Participant, Investigator, Outcomes Assessor)
Primary Purpose:	Other
Official Title:	A Randomized, Double-Blind, Placebo-Control Pilot Trial of Xuanfei Baidu Granules (XFBD), a Traditional Chinese Medicine (TCM), in Persons With COVID-19
Actual Study Start Date :	March 1, 2021
Estimated Primary Completion Date :	March 1, 2022
Estimated Study Completion Date :	September 1, 2022

https://clinicaltrials.gov/ct2/show/NCT04810689

Guidance for Corona Virus Disease 2019



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- Recovery Period:
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https://mp.weixin.qq.com/s/nOAmosQ4YqkXHKdJbBE9GA

宣肺败毒方 Xuan Fei Bai Du Fang (Lung Ventilating and Detoxifying Formula)

- *Ma Huang* (Herba Ephedrae) 6g
- *Ku Xing Ren* (Semen Armeniacae Amarum) 15g
- *Shi Gao* (Gypsum Fibrosum) 30g
- *Yi Yi Ren* (Semen Coicis) 30g
- *Cang Zhu* (Rhizoma Atractylodis) 10g
- *Guang Huo Xiang* (Herba Pogostemonis) 15g
- *Qing Hao* (Herba Artemisiae Annuae) 12g
- *Hu Zhang* (Rhizoma et Radix Polygoni Cuspidati) 20g
- *Ma Bian Cao* (Herba Verbenae) 30g
- *Lu Gen* (Rhizoma Phragmitis) 30g
- *Ting Li Zi* (Semen Lepidii) 15g
- *Ju Hong* (Exocarpium Citri Rubrum) 15g
- *Gan Cao* (Radix et Rhizoma Glycyrrhizae) 10g

宣肺败毒方 Xuan Fei Bai Du Fang (Lung Ventilating and Detoxifying Formula)

- 麻黄 *Má Huáng* (Herba Ephedrae) contains ephedrine alkaloids and the use may be restricted or prohibited. Substitution options include *Xiang Ru* (Herba Moslae), *Di Long* (Pheretima), *Ku Xing Ren* (Semen Armeniacae Amarum) and *Zi Su Zi* (Fructus Perillae).

Drug: Xuanfei Baidu Granules

- XFBD (administered as 1 packet of granules dissolved in warm water) orally twice daily for 14 day, 1 hour after food in the morning and at night with at least 8 hours in between doses

https://clinicaltrials.gov/ct2/show/NCT04810689

Placebo Comparator

- Placebo (administered as 1 packet of granules dissolved in warm water) orally twice daily for 14 day, 1 hour after food in the morning and at night with at least 8 hours in between doses

https://clinicaltrials.gov/ct2/show/NCT04810689

Primary Outcome Measures

1. Feasibility of recruitment
2. Participation Rate
3. Side Effects and Safety Profile
4. Rate of hospitalization or death

https://clinicaltrials.gov/ct2/show/NCT04810689

Secondary Outcome Measures

1. Symptom Severity Score
2. Study agent compliance
3. Symptom monitoring compliance
4. COVID-19 testing compliance
5. Hospital-free days
6. Adverse Events
7. Grade 3 and 4 adverse events
8. Viral load

https://clinicaltrials.gov/ct2/show/NCT04810689

Other

- Inclusion Criteria
- Exclusion Criteria

https://clinicaltrials.gov/ct2/show/NCT04810689

More Information

- Responsible Party: Darcy Spicer M.D., Associate Professor, University of Southern California
- ClinicalTrials.gov Identifier: NCT04810689
- Other Study ID Numbers: HS-20-00632

or by calling (206) 517-4541

Opportunity: Chinese Herbal Medicine for Suspected COVID-19 Symptoms

The **Seattle Institute of East Asian Medicine (SIEAM) and the Center for Integrated Care (CIC)** is offering telehealth visits for Chinese herbal medicine to support patients with suspected COVID-19 related symptoms.

Patients can receive virtual consults through the SIEAM's teaching clinic by SIEAM faculty, with masters and doctoral students observing.

Patients will have the following virtual appointments: 1) screening visit, 2) consults for the duration of your symptoms or until you decide to stop treatment. We will also follow up with you between consults. An individualized Chinese herbal formula will be recommended by your provider that can either be picked up curbside from the school or mailed to you. Costs include $25 for consultations + cost of herbs and shipping/delivery (if necessary).

For patients who are interested in participating in research, your treatment information could be included in a study. You will receive the same screening visit, consults, and follow up between consults. Data collected will include demographic information, changes in symptoms over time, as well as herbs dispensed and utilized. This study will collect and disseminate data to help inform the larger community of East Asian medicine practitioners.

Who is eligible to participate in the study? You may qualify if you answer **yes** to all 3 questions:

- **I am at least 18 years of age**
- **I have experienced one or more of these symptoms in the last 28 days:** cough, fever, shortness of breath, diarrhea, nausea, or abdominal pain OR am at a high risk of exposure.
- **I have a Primary Care Provider.** Have you contacted your primary care provider (PCP)? If no, you will need to do so to participate in the trial. Please contact your primary care provider to inform him or her that you are not feeling well. You will be required to provide your PCP's contact information during your screening appointment.

There is no compensation for this study.

Who do I contact for additional information?
To learn more and to find out if you are qualified, call the Seattle Institute of East Asian Medicine clinic at (206) 517-4541 or email ktaromina@sieam.edu

APPROVED: 04/11/2020

Brief Summary

- The purpose of the study is to design and execute a prospective, longitudinal, descriptive cohort study in a pragmatic clinical practice for adults with symptoms that may be related to COVID-19.

https://clinicaltrials.gov/ct2/show/NCT04380870

Detailed Description

- The purpose of this study is to design and execute a prospective, longitudinal, descriptive cohort study in a pragmatic clinical practice for adults with symptoms that may be related to COVID-19 infection who participate in Chinese herbal medicine (CHM) telehealth visits and take CHM. CHM includes over 400 medicinal substances and CHM formulas are individualized at each visit according to the patient's presentation. CHM has been used to treat cough, shortness of breath, and fatigue and mechanisms of action have been investigated for SARS and H1N1 influenza prevention and treatment by anti-inflammatory effects and antiviral activity. Yet, there is a gap in our understanding of the clinical application of CHM in a community sample of individuals experiencing symptoms that may be related to COVID-19. The investigators have no pragmatic clinic data about the use of CHM for coronaviruses.

Detailed Description

- Safe and effective treatment of symptoms associated with COVID-19 is a top international priority and research is needed to better understand if CHM is a safe intervention to treat symptoms. Further, dissemination of trustworthy CHM treatment approaches for this complex and emergent condition is needed within the CHM and scientific communities.

https://clinicaltrials.gov/ct2/show/NCT04380870

Study Design

Study Type :	Observational
Estimated Enrollment :	500 participants
Observational Model:	Ecologic or Community
Time Perspective:	Prospective
Official Title:	Describing Chinese Herbal Medicine Telehealth Care for Symptoms Related to Infectious Diseases Such as **COVID-19**: A Descriptive, Longitudinal, Pragmatic Cohort Study
Actual Study Start Date :	May 11, 2020
Estimated Primary Completion Date :	December 11, 2021
Estimated Study Completion Date :	May 11, 2025

https://clinicaltrials.gov/ct2/show/NCT04380870

Study Design

Condition or disease	Intervention/treatment
Coronavirus Infection	Dietary Supplement: Chinese Herbal Medicine

- Individualized CHM dispensed either as raw herbs to be decocted at home or granule
- Follow up at 24- and 48-hours after each telehealth visit.
- Additional follow up at 3, 6 and 12 months.

https://clinicaltrials.gov/ct2/show/NCT04380870
KIOM-SAR 2020 International Research Conference Abstracts / Integrative Medicine Research 9 (2020) 100498

More Information

- Responsible Party: Katherine Taromina, DACM, Instructor, Supervisor, Center for Integrated Care
- ClinicalTrials.gov Identifier: NCT04380870
- Other Study ID Numbers: 01-04-20

Other

- Medical Herbs Inhibit Inflammation Directing T Cells to Kill the COVID-19 Virus (NCT04790240)
- Assessment of Efficacy of KAN-JANG® in Mild COVID-19 (NCT04847518)
- Efficacy and Safety of High-dose Vitamin C Combined With Chinese Medicine Against Coronavirus Pneumonia (COVID-19) (NCT04664010)

The Process of Drug Development

https://www.lanl.gov/museum/news/newsletter/2018/03/drug-approval.php

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清肺排毒汤
Qing Fei Pai Du Granules


清肺排毒颗粒


清肺解毒颗粒
QingFei PaiDu Keli


清肺排毒汤


喜仙翁
清肺排毒汤
Qingfei Paidu Tang


GRIFFO
Qing Fei
pai du


LEKON HERB EXTRACT
QING FEI PAI DU TANG
清肺排毒湯

COVID-19 and TCM: An Update on the FDA-Approved Clinical Studies

John K. Chen, Ph.D., Pharm.D., O.M.D., L.Ac.
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