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Effectiveness of ammonium chloride in reducing viral load

Submission date
05/11/2025

Recruitment status
No longer recruiting

Registration date
27/11/2025

Overall study status
Completed

Last Edited
12/11/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A comparison is made between two dietary supplement formulations given early to adults with confirmed COVID-19 or seasonal influenza who attend the outpatient clinic or emergency department. One formulation contains 500mg ammonium chloride plus 2,000 IU vitamin D (ACF) and the other contains only 2,000 IU vitamin D (VDF). Both are enteric-coated, sustained-release tablets with marketing authorization in Greece.

Who can participate?
Adults (≥18 years) with a positive rapid test for SARS-CoV-2 or influenza A/B are recruited at Sotiria Hospital and En Ygeia Clinic in Athens. Participants are randomly assigned in a double-blind manner to ACF or VDF. One capsule is taken every 12 hours for 10 days in addition to usual medical care.

What does the study involve?
Viral load is measured three times (day 1; days 3–5; days 10–11), while symptoms and serious outcomes (hospitalization, need for oxygen, ICU admission, intubation, death) are recorded for 30 days. The primary outcome is defined as a reduction in viral load. Secondary outcomes include duration and severity of symptoms and the rates of the serious outcomes listed above.

What are the possible benefits and risks of participating?
Direct benefit to participants cannot be guaranteed. Both products are marketed dietary supplements and are monitored for any side effects or intolerance; study treatment is discontinued if needed. Data are collected by trained staff, handled under GDPR and national regulations, analyzed in aggregate, and stored securely. Participation is voluntary and based on written informed consent. Results are submitted to peer-reviewed journals and presented at scientific meetings.

When is the study starting and how long is it expected to run for?
May 2024 to April 2025, with the first participant enrollment scheduled for September 2024.

Where is the study run from?
The study is run from Sotiria Hospital (Athens, Greece) and En Ygeia Clinic (Athens, Greece).

Coordination and data management are provided by the Research Group of Clinical Pharmacology and Pharmacogenomics, Department of Pharmacy, National and Kapodistrian University of Athens.

Who is funding the study?
1. Metron Nutraceuticals, LLC, USA.
2. HELP SA, Greece.

Who is the main contact?
Prof. Nikolaos Drakoulis (Corresponding investigator), Faculty of Pharmacy, National and Kapodistrian University of Athens, drakoulis@pharm.uoa.gr

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Nikolaos Drakoulis

ORCID ID
https://orcid.org/0000-0002-7545-8089

Contact details
Panepistimiopolis Zografou
Athens
Greece
15771
+306944373647
drakoulis@uoa.gr

Type(s)
Scientific, Principal investigator

Contact name
Prof Helena Maltezou

ORCID ID
https://orcid.org/0000-0003-0264-3547

Contact details
National Public Health Organization
Athens
Greece
15123
+302105212173
e.maltezou@eody.gov.gr

Type(s)
Principal investigator

Contact name
Prof Garyphalia Poulakou

ORCID ID
https://orcid.org/0000-0003-0778-0006

Contact details
Infectious Diseases Clinic, 3rd University Clinic of Internal Medicine ; Sotiria Hospital for Respiratory and Thoracic Diseases
Athens
Greece
11527
+30210 7777737
gpoul@med.uoa.gr

Type(s)
Principal investigator

Contact name
Dr Constantine Chalkias

Contact details
22, Pagka street
Athens
Greece
11524
+302106996103
en.ygeia@gmail.com

Additional identifiers

Protocol serial number
Sotiria GH 14328/17-05-2025

Study information

Scientific Title
Effectiveness of a sustained-release ammonium chloride formulation in reducing the viral load of patients with COVID-19 or influenza

Acronym
ACTEarly

Study objectives
Objective 1. To estimate the comparative effectiveness of ACF over VDF in reducing the viral load in patients with SARS-CoV-2 or seasonal influenza (A or B) virus infection attending the Outpatients Clinic or the Emergency Departments of hospitals.
Objective 2. To estimate the comparative effectiveness of ACF over VDF in reducing the duration and/or severity of symptoms and the rate of severe outcomes* in patients with Sars-CoV-2 or seasonal influenza (A or B) virus infection attending the Outpatients Clinic or the

Emergency Departments of hospitals.
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*Defined as at least one of the following outcomes: hospitalization (applies only to outpatients), oxygen administration, admission to ICU, mechanical ventilation, or death.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/05/2024, Sotiria Hospital Scientific Council (152, Mesogeion Avenue, Athens, 11527, Greece; +30 210 7757156, internal 3401; epi.symb@sotiria.gr), ref: 14328/17-05-2024

Study design
Multicenter observational double-blind randomized comparative effectiveness pilot study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Mild or moderate COVID-19 or seasonal influenza infection

Interventions
Eligible participants were assigned in a 1:1 ratio to receive either the ACF formulation (ammonium chloride 500 mg + vitamin D 2000 IU) or the VDF formulation (vitamin D 2000 IU only).
Assignment was implemented through identical, pre-packaged study formulations, each bearing a unique LOT number corresponding to one of the two formulations.
Treating physicians dispensed the study products sequentially (1:1) according to the supplied kits.
Neither investigators nor participants were aware of the formulation identity; the blinding code was held solely by the manufacturer and disclosed only after completion of enrolment and data collection.
Both formulations were enteric-coated, sustained-release tablets administered orally, one tablet every 12 hours for 10 consecutive days.

Samples collected
-Nasopharyngeal swabs for RT-PCR quantification of SARS-CoV-2 or Influenza A/B were obtained at Day 1 (baseline), Day 3–5, and Day 10–12.
-Clinical follow-up data (symptom duration and severity, hospitalization, oxygen supplementation, ICU admission, intubation, death) were recorded prospectively and via telephone follow-up through Day 30.

Intervention Type
Supplement

Primary outcome(s)
Reduction of viral load, measured using RT-PCR cycle threshold (Ct) values obtained at baseline (Day 1), Day 3–5, and Day 10–12

Key secondary outcome(s))
1. Duration and severity of symptoms for 30 days documented through structured symptom diary and investigator follow-up at Day 30
2. Incidence of hospitalization (for outpatients) confirmed through clinical charts and hospital admission logs within 30 days of enrolment
3. Need for oxygen supplementation confirmed through clinical charts and hospital admission logs within 30 days of enrolment
4. ICU admission confirmed through clinical charts and hospital admission logs within 30 days of enrolment
5. Intubation confirmed through clinical charts and hospital admission logs within 30 days of enrolment
6. Death verified via hospital documentation, within 30 days of enrolment

Completion date
30/04/2025

Eligibility

Key inclusion criteria
Laboratory testing verified SARS-CoV-2 or Influenza A or Influenza B infection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Age <18 years
2. Pregnancy or lactation
3. Denial of informed consent
4. Known allergy to study components
5. Organ transplantation
6. Frailty score ≥5

Date of first enrolment
01/09/2024

Date of final enrolment
01/04/2025

Locations

Countries of recruitment
Greece

Study participating centre
Sotiria General Hospital
152, Mesogeion Ave.
Athens
Greece
11527

Study participating centre
En Ygeia Clinic
22, Pagka Street
Athens
Greece
11524

Sponsor information

Organisation
National and Kapodistrian University of Athens

ROR
https://ror.org/04gnjpq42

Funder(s)

Funder type
Industry

Funder Name
Metron Nutraceuticals, LLC

Funder Name
HELP Pharmaceuticals SA

Results and Publications

Individual participant data (IPD) sharing plan
Deidentified individual participant data (IPD) underlying the results reported in this study, including RT-PCR cycle threshold (Ct) values, symptom duration, and adverse events, will be available upon reasonable request. Data will be made available beginning three months after publication and will remain accessible for five years following publication.
All shared data will be fully anonymized prior to release to ensure participant confidentiality. Written informed consent for participation and data handling was obtained from all participants, and the study was approved by the Scientific Council of Sotiria Hospital (ref. 14328/17-05-2024). There are no known legal or ethical restrictions preventing data sharing beyond standard GDPR compliance.
Requests should be directed to Prof. Nikolaos Drakoulis (drakoulis@uoa.gr) and will require submission of a brief research proposal and completion of a data access agreement.

IPD sharing plan summary
Available on request