

BioBlock nasal spray against COVID-19

Submission date 02/05/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/02/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

The nose is both a source of pathogens and a critical port of entry for infectious agents such as viruses and bacteria. Prevention of SARS-CoV-2 infection at the point of nasal entry is a novel strategy that has the potential to help contain the ongoing pandemic. Households are high-risk settings for SARS-CoV-2 transmission. Those with confirmed or suspected infections are required to isolate at home, putting other members of their household at an increased risk.

There is a need for research exploring whether directly applying SARS-CoV-2 antibodies into the upper respiratory airway is effective as a prevention or treatment strategy in an exposed household setting. The study team will test the antiviral preparation prepared from colostrum from cows immunized with SARS CoV-2 spike protein.

Who can participate?

Adults with confirmed COVID-19 and their SARS-CoV-2 RNA negative adult household members recruited from two participating family physician practices.

What does the study involve?

The patients and their households will be allocated to receive either BioBlock treatment or to receive an identical spray with no active medicine (placebo), with an equal chance of being in either group (like tossing a coin). Patients will administer BioBlock or placebo for 14 days. COVID-19 patients will have their symptoms recorded until up to a maximum of 21 days follow-up. Respiratory samples will be collected at 14 days. Household members will have their symptoms recorded until up to a maximum of 14 days and respiratory samples collected at 14 days.

What are the possible benefits and risks of participating?

There is currently no evidence relating to the benefits and risks of using this nasal spray. Administering Bioblock nasal spray to people with COVID-19 might help them fight the infection

and to people without COVID-19 to prevent them from infection. It is possible that using nasal spray could cause some unwanted effects, including irritation, or allergic reactions. To mitigate these effects individuals with selected conditions will be excluded from the study.

Where is the study run from?
University of Tartu (Estonia)

When is the study starting and how long is it expected to run for?
From February 2021 to December 2021

Who is funding the study?
AS CHEMI-PHARM (Estonia)

Who is the main contact?
Prof Anneli Uusküla
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Protocol v1

Study information

Scientific Title
Cluster randomized, controlled, triple-blind trial assessing the efficacy of intranasally administered virus-neutralizing bovine colostrum supplement in preventing SARS-CoV-2 infection in household contacts of SARS-CoV-2 positive individuals

Acronym

BioBlock

Study objectives

1. In close contacts of a SARS-CoV-2 carrier, using BioBlock nasal spray would be associated with a lower SARS-CoV-2 infection rate at day 14
2. In patients with confirmed SARS-CoV-2 infection, using BioBlock nasal spray would be associated with improved clinical outcomes at day 21

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/04/2021, Research Ethics Committee of the University of Tartu (University of Tartu, Raekoja plats 9, 51004 Tartu, Estonia; +372 737 6215; eetikakomitee@ut.ee), ref: 339/T-1

Study design

Cluster randomized triple-blinded controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of COVID-19 (SARS-CoV-2 infection) among in household contacts of SARS-CoV-2 positive individuals

Interventions

This is a cluster randomized placebo-controlled trial of household contacts of laboratory-confirmed cases of COVID-19 compared to an uninfected control group of household contacts. Participants, investigators, and outcome assessors will be blind to allocation. The placebo and BioBlock sprays will be blinded at the site of manufacture.

At a minimum, enrolled household cases and contacts will complete data and specimen collection at enrollment (Day 1) and for 14 days of follow-up, with at least two follow-up visits interviews for household contacts and three follow-up visits for index cases. Household (index case and household contacts) respiratory samples will be collected for SARS-CoV-2 RNA testing at 1 and 14 days. Questionnaires will be completed by Index cases at 1, 7, 14, and 21 days and by SARS-CoV-2 PCR negative household contacts at 1, 7, 14 days.

Intervention Type

Device

Phase

Phase II

Drug/device/biological/vaccine name(s)

A nasal spray containing colostrum preparation of SARS-CoV-2 antiviral antibodies

Primary outcome(s)

Rate of COVID-19 infection in household members measured using PCR swab taken at 1 and 14 days

Key secondary outcome(s)

Severity of COVID-19 infection measured using the time taken for all symptoms to resolve (days) from participant questionnaires at 1, 7, 14, 21 days for index cases and 1, 7, 14 days for SARS-CoV-2 PCR negative household contacts

Completion date

30/12/2021

Eligibility**Key inclusion criteria**

Index case:

1. Confirmed case of COVID-19 infection with at least one SARS-CoV-2 PCR negative person household contact
2. Aged ≥ 16 years

Household contacts:

1. SARS-CoV-2 PCR negative household contact of the index case
2. Aged ≥ 16 years

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Current exclusion criteria as of 27/08/2021:

1. Aged < 16 years
2. Pregnancy
3. Use of active cancer treatment
4. Use of biological treatment
5. Previously confirmed COVID-19
6. Any organ transplantation
7. Single person household
8. Requires hospitalisation prior to study start
9. Required to take regular medications administered by inhalation, or via the naso- and oropharyngeal route
10. Asthma
11. Known allergies to BioBlock components

Previous exclusion criteria:

1. Aged <16 years
2. Pregnancy
3. Use of active cancer treatment
4. Use of biological treatment
5. Previously vaccinated against COVID-19
6. Previously confirmed COVID-19
7. Any organ transplantation
8. Single person household
9. Requires hospitalisation prior to study start
10. Required to take regular medications administered by inhalation, or via the naso- and oropharyngeal route
11. Asthma
12. Known allergies to BioBlock components

Date of first enrolment

12/05/2021

Date of final enrolment

30/12/2021

Locations

Countries of recruitment

Estonia

Study participating centre

Telliskivi Perearstikeskus OÜ

Telliskivi 1

Tallinn

Estonia

10611

Study participating centre

Mustamäe ja Nõmme Perearstikeskus OÜ

Ehitajate tee 27

Tallinn

Estonia

12618

Sponsor information

Organisation

University of Tartu

ROR

<https://ror.org/03z77qz90>

Funder(s)

Funder type

Industry

Funder Name

CHEMI-PHARM AS

Results and Publications

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?
Protocol article		31/01/2022	02/02/2022	Yes	No