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BioBlock nasal spray against COVID-19

Submission date	Recruitment status	[_] Prospectively registered
02/05/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2022	Infections and Infestations	[_] 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

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
10/02/2021

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

Age group
Mixed

Sex

Both

Target number of participants
218 household contacts and 124 SARS-CoV-2 positive index patients

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

Sponsor details
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Sponsor type
University/education

Website
http://www.ut.ee

ROR
https://ror.org/03z77qz90

Funder(s)

Funder type
Industry

Funder Name
CHEMI-PHARM AS

Results and Publications

Publication and dissemination plan
Planned publications in a high-impact peer-reviewed journal.

Intention to publish date
30/04/2022

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