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Plasma exchange therapy with the crossflow membrane filtration method for post-COVID-19 conditions

Submission date
07/06/2024

Recruitment status
No longer recruiting

Registration date
10/06/2024

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Many patients with COVID-19 infection continue to have non-specific symptoms months after infection, such as persistent fatigue, cognitive issues, dyspnea (breathlessness), headaches, myalgias (muscle pain), sleep disturbances, anosmia/ageusia (loss of smell/taste), and post-exertion malaise (tiredness). These ongoing symptoms are referred to as post-COVID syndrome or long COVID. The rising number of long/post COVID cases poses a challenge to global health systems. The mechanisms behind post-COVID syndromes may include inadequate immune responses, autoimmunity activation, pro-inflammatory biomarkers persistence, endothelial dysfunction, and changes in the gut microbiota. Plasmapheresis, also known as plasma exchange, is a procedure that removes, treats and returns blood plasma to the body's circulation. Plasma exchange has shown moderate to significant clinical improvement in various inflammatory, autoimmune, and neurological diseases associated with autoantibodies by reducing blood levels of pro-inflammatory cytokines and autoimmune markers. The aim of this study is to evaluate the effect of plasmapheresis in long COVID patients compared to patients receiving placebo treatment.

Who can participate?
Patients aged 18-65 years with long COVID

What does the study involve?
Participants are randomly allocated to one of two groups. The treatment group undergoes plasmapheresis treatment with reinfusion of the cellular components at five day sessions with almost two days of rest in between. The placebo group undergoes dummy plasmapheresis treatment with the same setup as the treatment group but without the removal of plasma (reinfusion of both cellular and plasma components back to the patient). Clinical and laboratory outcomes will be assessed on day 0, day 5, day 10 day 28 and day 90

What are the possible benefits and risks of participating?
Participants will not receive financial compensation as the research is conducted without monetary backing. They will, however, earn the profound gratitude of the medical team and

future patients may benefit from the study's findings. Occasionally, drawing blood from the arm may cause bruising, slight pain, or discomfort, and in extremely rare cases, an infection at the infusion site. The researchers will take all preventive measures to minimize these risks. Sometimes patients may feel lightheaded or slightly dizzy, especially during the procedure. This will take only a few minutes and decreases quickly. All information provided and test results will be treated confidentially. The researchers have the responsibility to inform the participants of all blood test results and to advise them on any treatment they think they need.

Where is the study run from?
Academic Hospital Paramaribo (Suriname)

When is the study starting and how long is it expected to run for?
November 2023 to December 2024

Who is funding the study?
Academic Hospital Paramaribo (Suriname)

Who is the main contact?
Dr Rosita Bihariesingh-Sanchit, rbihariesingh@azp.sr

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

CMWO:09/2024

Study information

Scientific Title
Sur-Long-Covid Trial: a placebo-controlled, double-blind proof of concept trial on the efficacy and safety of crossflow membrane plasmapheresis on long COVID-19 outcomes

Study objectives
Plasma exchange with Crossflow membrane filtration is a safe and effective treatment for long-COVID conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/06/2024, Medical Ethical Review Committee of the Ministry of Health of Suriname (Henck Arron straat 64, Paramaribo, 0, Suriname; +597 (0)477601; secdir.volksgezondheid@gov.sr), ref: CMWO:09/2024

Study design
Single-centre double-blinded placebo-controlled randomized clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Telephone

Study type(s)
Quality of life, Treatment, Safety, Efficacy

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

Health condition(s) or problem(s) studied
Long COVID

Interventions
Participants will be randomized 1:1 to one of the following groups:
1. Placebo arm, i.e. patients will receive dummy plasmapheresis treatment with the same setup as the treatment arm but without the removal of plasma (reinfusion of both cellular and plasma components back to patient)
2. Treatment arm, i.e. patients will receive plasmapheresis treatment with reinfusion of the cellular components. Plasmapheresis five day sessions of plasma exchanges with almost two days rest in between.

Clinical and laboratory outcomes will be assessed on day 0, day 5, day 10 day 28, and day 90.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Crossflow membrane filtration with the Hemoclear device

Primary outcome measure
Long-term COVID symptomatology measured using physical and cognitive questionnaires /parameters (Chalder scale, FAS, Promis) at baseline and 90 days

Secondary outcome measures
1. Observation of the evolution of the fatigue measured by the percentage of patients whose fatigue has decreased by 30% on the Chalder scale at 90 days compared to its initial state measured at baseline
2. Quality of life measured using SF-36 at baseline, day 28 and 90 days
3. Clinical symptoms, functioning, and quality of life evaluated using PROMIS at baseline, day 28 and 90 days
4. Long COVID fatigue symptomology measured by the Fatigue Assessment Scale (FAS) at baseline, day 28 and 90 days
5. Rate and evolution of autoimmune antibody markers within 90 days (posthoc analysis based on funding) analysed with Luminex/ELISA at baseline, day 5, day 10, day 28 and day 90

Overall study start date
01/11/2023

Completion date
01/12/2024

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Have had a confirmed SARS-COV2 infection (RT PCR) for at least 6 months
3. Have had at least three of the following symptoms for more than 6 months: fatigue, post-exercise malaise, shortness of breath, headache, diffuse myalgia/arthralgia, neuropathic pain, cognitive impairment, anosmia/ageusia
4. Above symptoms have an impact on daily activities, and/or have been on sick leave for more than 3 months, and/or going to bed for more than 2 hours a day
5. Have given free and informed written consent
6. Affiliated with sickness cost security
7. A score of 6 out of 11 or more on the Chalder fatigue questionnaire and a score of 65 out of 100 or less on the short physical function of 36 subscale 15

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. With suspicion of COVID-19 but not confirmed by RT-PCR test
2. Known history of any other pathology that could be confused with the diagnosis of long COVID: multiple sclerosis, autoimmune disease (lupus and Gougerot syndrome, inflammatory muscle disease, and myasthenia gravis), untreated hypothyroidism, major depression, regular use of narcotics
3. Unable to travel
4. Congenital or drug-induced coagulation disorders (oral or parenteral anticoagulation)
5. Contraindications to plasmapheresis such as lack of peripheral venous access or unstable cardiac pathology
6. Pregnant or breastfeeding women

Date of first enrolment
04/06/2024

Date of final enrolment
04/09/2024

Locations

Countries of recruitment
Suriname

Study participating centre
Academic Hospital Paramaribo
Flustraat 1-3
Paramaribo

Suriname
0000

Sponsor information

Organisation
Academic Hospital Paramaribo

Sponsor details
Flustraa1-3
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Sponsor type
Hospital/treatment centre

Website
https://www.azp.sr

ROR
https://ror.org/01ky0w731

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Hospital Paramaribo

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Rosita Bihariesingh-Sanchit (rbihariesingh@azp.sr or bihariesinghr@gmail.com)

IPD sharing plan summary

Available on request