Lactoferrin in the treatment of Long COVID

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To reduce fatigue symptoms with the use of a bovine lactoferrin supplement in patients suffering from Long COVID.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50577

Source
ToetsingOnline

Brief title
LARGO-study

Condition

- Viral infectious disorders

Synonym
Long-COVID

Research involving
Human

Sponsors and support

Primary sponsor: Longziekten
Source(s) of monetary or material Support: Bonusan B.V.

Intervention

Keyword: Clinical trial, food supplement, Lactoferrin, Long-COVID

Outcome measures

Primary outcome

Primary endpoint: Fatigue symptoms (measured with FAS) within 6 weeks and 3 months after initiation of intervention.

Secondary outcome

Secondary endpoints: Cognitive function (CFQ), Anxiety and depression (HADS), Inflammatory parameters in blood (e.g. IL-6, hsCRP) and muscle strength (Handgrip strength and 30sec Sit-to-Stand test).

Study description

Background summary

Lactoferrin is an antimicrobial iron-binding glycoprotein that can modulate the immune system and lower oxidative stress levels. Recent evidence indicates a faster recovery from (acute) COVID-19 after using (bovine) lactoferrin supplements. Yet, the effect of lactoferrin in patients suffering from long COVID has not yet been studied. Since immune dysregulation, higher oxidative stress levels and viral persistence could explain at least part of the Long COVID persisting symptoms, including fatigue, muscle weakness, cognitive dysfunction and anxiety and depression, we want to initiate a clinical- and laboratory study looking into the effects of bovine lactoferrin in these patients.

Study objective

To reduce fatigue symptoms with the use of a bovine lactoferrin supplement in patients suffering from Long COVID.

Study design

Investigator-initiated double-blind randomized controlled trial.

Intervention

Lactoferrin 4 x 300 mg capsules (total 1200 mg/day) (Bonusan) versus identical

placebo capsules; given daily during 6 weeks.

Study burden and risks

Bovine lactoferrin is a food ingredient that has been used for years in infant and follow-up formulae and is an approved food supplement. It has antimicrobial properties and can modulate the immune system and lower oxidative stress levels.
The burden is regarded as low; participants have to take 2 capsules 2 times a day for 6 weeks (total 1200 mg daily). Lactoferrin in these concentrations is considered safe by the European Food Safety Authority (EFSA) and is without risk of adverse effects. The 6- and 12-week visits will be scheduled as much as possible together with regular doctor's visits. During these time points, 18 ml of blood will be taken, as well as questionnaires and 2 muscle strength tests.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Subjects aged 18-70 years with proven COVID-19 (positive COVID-19 RT-PCR- or antibody test)
- Persistent or newly developed long COVID symptoms at least 12 weeks post-primary SARS-CoV-2 infection
- Patients with a positive COVID-19 RT-PCR- or antibody test not older than 9 months

Exclusion criteria

- Patients admitted to the ICU (COVID-19-related)
- COVID-19-related cardiac or pulmonary tissue damage
- Acute infection or current systemic immunological disorders
- Oral and/or inhaled use of corticosteroids or use of other immune-modulatory medication
- Current psychiatric disorders
- Communication difficulties
- Pregnant or lactating women
- Age >70 years
- Patients with milk allergy or a known or suspected allergy or any contraindications to lactoferrin or microcrystalline cellulose (lactoferrin can be used by individuals with lactose intolerance)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2022
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79017.100.21
Other	NL9742