Lactoferrin in the treatment of Long COVID

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21473

Source
Nationaal Trial Register

Brief title
LARGO

Health condition

Long COVID

Sponsors and support

Primary sponsor: Stichting O&O Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Bonusan B.V.

Intervention

Outcome measures

Primary outcome

- Do fatigue symptoms diminish faster with the use of lactoferrin combined with usual care compared to usual care solely?

Secondary outcome

- Do anxiety and depressive symptoms diminish (faster) with the use of lactoferrin?
- Does the use of lactoferrin (faster) improve cognitive function?
- Does muscle strength recover (faster) with the use of lactoferrin?
- Does the use of lactoferrin have an effect on inflammatory blood parameters?
- How do changes in subjective health parameters correlate with circulating biomarkers?

Study description

Background summary

Rationale: 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.
Main 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.
Study population: Long COVID patients aged 18-70 years with confirmed COVID-19 (positive RT-PCR or antibody test not older than 9 months).
Intervention (if applicable): Lactoferrin 4 x 300 mg capsules (total 1200 mg) (Bonusan) versus identical placebo capsules; given daily during 6 weeks.
Main study parameters/endpoints: Primary endpoint: Fatigue symptoms (measured with FAS) within 6 weeks and 3 months after initiation of intervention.
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 objective

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

Study design

baseline, 6 and 12 weeks

Intervention

Lactoferrin 1200 mg/day versus Placebo

Contacts

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Eligibility criteria

Inclusion criteria

- 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
- Adult patients with age >18 years

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-01-2022
Enrollment:	72
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-09-2021
Application type:	First submission

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
NTR-new	NL9742
Other	MEC-U : MEC-U 21.081

Study results