# Lactoferrin in the treatment of Long COVID

Published: 08-12-2021 Last updated: 05-04-2024

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

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeViral 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**

#### **Public**

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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