

PRESS RELEASE

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Dutch treatment based on the anaesthetic lidocaine improves quality of life and provides symptomatic relief in patients with severe Long COVID

Today, the medical journal *eClinicalMedicine*, part of The Lancet Discovery Science (Lancet Group), published the results of a treatment with the well-known anaesthetic lidocaine, specially adapted for patients with severe Long COVID symptoms. The treatment was developed by physicians at Excellent Care Clinics, an independent clinic for anaesthesiology and pain management. An observational study has demonstrated that a lidocaine formulation, suitable for home administration, injected under the skin, leads to significant improvement in both physical and psychological symptoms in a group of 103 patients with Long COVID. Of the treated patients, 80% reported an improvement in symptoms. These improvements ranged from small but important steps forward for patients to the complete disappearance of typical Long COVID symptoms. The progress of home treatment was monitored via a specially developed app, among other methods. The medication was prepared by a hospital pharmacy. The collected data were subsequently analysed by researchers from Amsterdam UMC and Vrije Universiteit Amsterdam.

<https://www.sciencedirect.com/science/article/pii/S2589537025006157>

Self-administration under the skin

Lidocaine has long been known to have not only analgesic but also anti-inflammatory effects. For this reason, it is used by anaesthesiologists both during surgery and in pain medicine. For the treatment of pain complaints, the drug is usually administered only in hospital via infusion and under monitoring, due to the risk of side effects at higher blood plasma levels. For patients referred with pain complaints due to Long COVID, lidocaine was administered under the skin (subcutaneously) to avoid these high plasma levels. An excipient (cyclodextrin) was added to the injection fluid. As a result, patients could administer the drug themselves daily at home and did not need to come to the clinic. This was particularly important for severely disabled Long COVID patients, as clinic visits are often very burdensome and can cause worsening of symptoms. Home treatment was monitored remotely via an app and wearables. This allowed symptoms, vital signs and side effects to be monitored. Participants had been seriously ill for an average of 2.5 years. No serious side effects occurred. However, local skin irritations did occur at the injection sites.

Modifying a dysregulated immune system

In the article published today, the physicians and researchers explain why subcutaneous administration of the medication has likely made an important contribution to the significant improvements across the entire spectrum of Long COVID symptoms, while safety measurements showed that blood levels remained low. They suspect that this method of administration, under the skin, ensures higher absorption in the lymphatic system and lymph nodes (an important part of the immune system). This is likely to inhibit an overactive immune mechanism. The hypothesis is that a dysregulation of the immune system causes inflammation in multiple organ systems. This could explain why Long COVID patients experience so many, and often very severe, symptoms.

Prof. Jos Twisk, PhD, Professor of Applied Biostatistics and responsible for the data analysis commented: "The results achieved in this observational study approach the statistical power of a classic randomized clinical trial. A strong point is that measurements were also taken before treatment started, meaning patients serve as their own controls. There could be a placebo effect, but the effects found are much larger than would be expected from a placebo. In short: the results strongly suggest that the treatment is effective. Additional future clinical research can confirm this and then the precise effect and size compared to no treatment can be quantified. Based on this research, the effectiveness appears to be established."

Dr. Ivo Lutke Schipholt, senior researcher at the Faculty of Behavioural and Movement Sciences at Vrije Universiteit Amsterdam commented: "Our research into the role of the immune system in pain is gaining a new dimension with Long COVID. We see that lidocaine not only reduces the often severe (muscle) pain, but also typical Long COVID symptoms such as fatigue, sensory overload, concentration problems and Post Exertional Malaise (PEM). Further studies on effectiveness, dosing and mechanism of action now have high priority."

Cees-Jan Oostwouder, anaesthesiologist-pain specialist at Excellent Care Clinics, together with fellow anaesthesiologist-pain specialist Karin Vos and clinical researcher Dr. Coen van Kalken, one of the physicians behind the treatment, commented: "With this method of administration of a medication that has been used in anaesthesiology for 70 years, we see that a majority of our Long COVID patients emerge from a years-long hopeless situation. As a physician, it is fantastic to see how people get their lives back, wholly or partially. Every improvement means a world of difference for these patients."

Availability of the new treatment for severely ill Long COVID patients

Long COVID affects an estimated 400 million people worldwide. In the Netherlands, according to RIVM, approximately 400,000 people report having Long COVID symptoms. For about 100,000 of them, these symptoms are severe. For a large proportion of these patients, there is a very urgent need for help, while no proven effective therapy is yet available. The medication described is currently only available as a pharmacy preparation.

A randomized clinical trial into the precise effectiveness of the treatment is being prepared. According to the physicians and researchers, more insight is also needed into the optimal dosage per patient, the duration of administration, and the long-term effects.

<http://excellentcareclinics.nl/long-covid>

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Subcutaneous administration of the lidocaine medication