

1. Background

Thank you for your previous participation in the SOLIDARITY Finland trial. The SOLIDARITY Finland trial forms a part of the global, randomised, and adaptive SOLIDARITY Trial launched by the World Health Organization (WHO) in the spring of 2020, which involves centres from more than 40 countries.

The remdesivir trial of SOLIDARITY Finland was carried out in four university hospitals and nine hospital districts, in a total of 13 hospitals, covering approximately 70% of the Finnish population and involving more than 200 patients. The first phase of the trial measured mortality during hospitalisation, duration of treatment, need for ventilation support/intensive care, and serious adverse events.

Some COVID patients suffer from prolonged symptoms such as fatigue, headache, impaired concentration, and dyspnoea after the acute phase of the infection. These symptoms have been called long COVID. Our intention is to investigate these symptoms in more detail in the SOLIDARITY Finland Long-COVID trial.

2. Why have I been invited to participate in the trial?

A year ago, you were hospitalised due to a coronavirus infection and participated in the randomised SOLIDARITY Finland trial in which patients were randomly assigned to receive either standard hospital care or the remdesivir antiviral drug in addition to standard hospital care. To assess the effectiveness of treatment and the possible long-term effects of coronavirus infection, we are conducting a survey to determine patients' quality of life and possible symptoms.

3. What is the purpose of the trial?

Our intention is to investigate the symptoms and quality of life of people who have had COVID-19. We are studying the long-term symptoms of COVID-19 and experience of quality of life with the attached survey. This will allow us to better assess the medication and prognosis of future COVID patients.

You may not directly benefit from participating in the trial, but you will help us evaluate the effects of the antiviral drug in long-term monitoring. This is important information for those contracting a coronavirus infection in the future, for treating physicians to have as comprehensive information as possible about the effects of different medication options.

4. Is participation in the trial mandatory?

No, participating in the trial is voluntary. If you participate in the trial but decide to withdraw from it, you can do so at any time without explaining why. Your withdrawal will have no effect on your current or future care. If you decide to participate, you will be asked to sign a form giving your consent to participate in the trial.

5. What will happen if I participate?

If you decide to participate, you will be asked to fill in a survey form and sign a form giving your consent to participate in the trial. **Filling in the survey forms will take about 5 minutes.** No fee will be paid for participation in this trial. Submitting the surveys will result in no costs to you, you can submit your answers using the prepaid return envelope.

We will also approach test subjects with a reminder message after 10–14 days if we have not received the survey or a refusal to participate in the trial. **If you would like to respond to the survey by phone, you can suggest a suitable date and time and provide your phone number at the bottom of the consent form.**

6. Will the information I provide be kept confidential?

Yes, all information collected during the trial will be kept completely confidential. During the trial, a patient-specific research number is used to identify your personal information. Only principal researchers can link

your research number to your personal information. The results of this trial may be published or presented at scientific conferences, but your personal information will be treated anonymously in accordance with both the national Data Protection Act and the Personal Data Directive of the European Parliament and of the Council (95/46/EC). Your name will not be disclosed to other researchers or in reports or publications on this trial.

7. What will the information I provide be used for?

We hope that the results will be published in an international publication reporting on the effect of remdesivir on the long-term symptoms of coronavirus infection and quality of life. You cannot be identified from any of the research reports. We will also provide information on the results in Finland in a form that can be understood by lay people.

8. What will happen if I do not want to continue in the trial?

You have the right to discontinue your participation in long-term monitoring at any time before the end of the trial. After the discontinuation, only the information collected up to that point will be used in the trial.

9. What will happen if there is a problem?

We do not believe that you will experience any problems participating in the trial, but if you have any concerns, you can discuss them with the coordinator of the trial either by phone or email (contact information in section 12).

10. Who is organising the trial?

This trial is being carried out by the SOLIDARITY Finland research team, which consists of Finnish doctors and researchers working in Finnish hospitals and universities. Professor Kari Tikkinen from the University of Helsinki commissioned the trial and is its coordinator in Finland.

11. Who has evaluated and approved the trial?

The SOLIDARITY Finland Long-COVID trial has received a favourable opinion from the Research Ethics Committee of the Hospital District of Helsinki and Uusimaa. Fimea, TUKIJA, the Ministry of Social Affairs and Health and the participating hospital districts have also previously granted research permits for the SOLIDARITY Finland trial. The steering group of the trial ensures that the trial complies with good research practice.

12. How can I get in touch with the research team if I want more information about the trial?

If you have any questions about the trial, please contact the trial physician (Professor Kari Tikkinen; kari.tikkinen@hus.fi or tel. 040 651 0530).

PATIENT'S CONSENT

Long-term monitoring of the randomised multicentre trial exploring the effects of long COVID in hospitalised COVID patients (SOLIDARITY Finland Long-COVID)

I have been invited to participate in the aforementioned scientific trial.

I have read and understood the research bulletin given to me. I have read the report above and have received sufficient information on the trial and on the collecting, handling and disclosure of data in connection with that trial. I have had sufficient time to think about participating in this trial. I understand that participating in the trial is voluntary. I have the right, at any time during the trial and without explaining why, to discontinue my participation in the trial. Revoking my consent will result in no negative consequences for myself and will not affect my status as a client of health care services. I am aware that data collected up until the time when I revoke my consent may be used for research as part of the research material collected and of the safety assessment for the medication.

I hereby confirm with my signature that I consent to participate in the trial described in this document and that I voluntarily consent to be examined.

Signature

Name in block letters

Date

Date of birth or personal identity number

Home address