To the participant

Trial information for clinical trial assessing hospitalised patients with COVID-19 and severe hypoxia

Title

Low-dose hydrocortisone in patients with COVID-19 and severe hypoxia – the COVID STEROID Trial

Introduction

You are or have been admitted to hospital with severe COVID-19. We now ask if you want to give consent to participate in a clinical trial. The trial was commenced during emergency care, and your condition made us unable to ask you directly if you wanted to participate in the trial. Now that you're improving, we ask if you want to continue in the trial. You must fully understand what the trial is about and why we conduct it. Please read this participant information thoroughly. Participation in the trial is voluntarily, and you can refuse to participate or withdraw your consent at any time; this will not affect your current or future care.

The participation information will also be explained to you orally. During this conversation, you can ask questions. Feel free to bring a family member or friend to the conversation.

If you decide to continue to participate in the trial, we will ask you to sign the attached consent form. Please spend the time you need before you decide and remember that you are entitled to at least 24 hours to decide.

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel virus that can cause severe infection in the airways (COVID-19). COVID-19 was first described in China in December 2019. There is no specific treatment for COVID-19, and the current treatment is therefore supportive care.

Corticosteroids are recommended for patients with blood poisoning shock and severe respiratory failure caused by bacteria, but it is unclear if corticosteroids benefit patients with severe COVID-19. Some evidence suggest that corticosteroids are beneficial for COVID-19, but corticosteroids may cause severe adverse reactions. We hypothesise that corticosteroids benefit patients with severe COVID-19, but we cannot guarantee that this will be the case for you.

Aim

We aim to assess if corticosteroids (hydrocortisone) increases the number of days alive without life support (i.e. mechanical ventilation, blood pressure support, renal replacement therapy) in patients with COIVD-19 and severe hypoxia.

Methods

In this trial, you were either randomised to hydrocortisone (200 mg daily) or placebo (saline) for 7 days. The participants are treated in two different ways so that we can assess the effects of corticosteroids; this is done by comparing the participants receiving hydrocortisone with the participant not receiving active treatment (placebo group). At present, we do not know if you have received hydrocortisone or placebo. This will be undisclosed until the end of the trial.
At the end of the trial, we will compare the use of life support, incidence of side effects, length of stay in hospital, survival and health-related quality of life between participants receiving hydrocortison vs. placebo.
The trial is conducted in 1000 patients at 16 hospitals in Denmark. A year after participation, we will call you with a questionnaire about your health-related quality of life.

Gain from participation in the trial

You may gain from participation in the trial, but this is not certain. Participation in the trial can help us gain important knowledge about the best treatment for COVID-19. This knowledge will improve the care of future patients with COVID-19. The trial is associated with minimal risks as patients with a high risk of side effects are excluded from participation.

Who CAN participate?

You can participate in the trial if you are 18 years or older and hospitalised with COVID-19 and severe hypoxia requiring mechanical ventilation or high levels of oxygen therapy.

Who CANNOT participate?

You cannot participate, if you:

- Already receive treatment with corticosteroids
- Have a severe fungal infection
- Are allergic to hydrocortisone
- Have been mechanically ventilated for more than 48 hours

Women younger than 60 years of age must have a negative pregnancy test before participation in the trial.

Discontinuation of trial medications

You may at any time during the trial withdraw your consent without providing a reason for this. This will not affect your current or future treatment, and you get the same care as any other patient in the department.

The doctors may also choose to discontinue the trial medication. In this case, you will be notified and provided a reason for the discontinuation.

Disadvantages

The trial does not cause any disadvantages for you.

Adverse reactions, risks and complications

Hydrocortisone is a frequently used and well-known drug. The most common adverse reactions are edema, low potassium in blood, manifestation of latent diabetes mellitus or muscle atrophy. Serious side effects are uncommon. They include allergic reactions (very uncommon and usually not serious), infections (uncommon, but serious) and bleeding from the gastrointestinal tract (uncommon and usually not serious).

Saline has no side effects in the quantities used in the trial. If treated with saline, there is a risk that you will not receive the potential benefits of hydrocortisone.
There may be other risks in the trial, which we do not know of yet. If we suspect any adverse effects, which we haven't already told you about, we will inform you immediately.

Confidentiality

All information will be treated confidentially, and the trial results will be reported with full anonymity for you. The Medicines Agency, the Good Clinical Practice unit, the Sponsor and the site investigator have access to your hospital files to ensure that the trial is conducted as agreed upon. These persons are subject to professional secrecy.

Funding of the trial

Initiator and sponsor of the trial is Professor Anders Perner at Rigshospitalet in Copenhagen and doctors from several intensive care units and medical departments in Denmark. Together they have obtained private funding from The Novo Nordisk Foundation (5.000.000 DKK) and Rigshospitalet Research Funds (1.875.000 DKK). The money is being used for data collection and salaries for trial staff. Each trial site does not receive money for including participants in the trial. None of the investigators have financial affiliation with companies or foundations that could have interests in the outcome of this trial.

Insurance

You are covered by the hospital insurance.

Access to the trial results

When the trial is completed (expected December 2020), the results will be published in an international scientific journal. If you want information about the trial results, including any implications for you, please contact the investigators (contact details provided below).

Contact

With this information we hope that you have enough insight into the consequences of trial

participation to make the decision. Further information about the trial can obtained by contacting the investigators (contact details provided below).

Yours sincerely

Anders Perner

Professor, senior intensive care specialist, ph.d.

Department of Intensive Care, Rigshospitalet

Blegdamsvej 9, 2100 København Ø

Tel.: 3545 4131

E-mail: anders.perner@regionh.dk

[Name of primary investigator]

Doctor, ph.d.-student

Department of Intensive Care, Rigshospitalet

Blegdamsvej 9, 2100 København Ø

Tel.: 3545 4131

E-mail: marie.warrer.petersen.01@regionh.dk