



This document has been prepared according to Danish regulations. You may require additional/different information according to your national regulations. Please feel free to change the document and provide the relevant information.

Remember to delete this box and insert your contact details at the bottom of the letter.

Information about participation in a scientific study of critically ill patients admitted to the intensive care unit

You have been seriously ill and were in need of immediate treatment in the intensive care unit. You have participated in a medical research project. Because of your condition, we were not able to inform you and ask you directly if you wanted to participate in the study.

Now that you are improving, we will ask you if you want to continue participating in the study. You must fully understand what the study is about, and why we are conducting it. We kindly ask you to read the information below carefully.

You will be offered a conversation with a person from the research group, where you will be given a more in depth understanding of the study and you can ask questions. You are welcome to bring a family member, a friend or an acquaintance to this conversation.

If you decide to continue your participation in the study, we will ask you to sign the attached consent form. Remember that you have the opportunity to consider your decision before signing.

It is voluntary to participate in the study. You may at any time and without giving a reason, withdraw your consent. Participation in the study will not have any influence on your treatment in general.

Background

Critically ill patients admitted to the intensive care unit are at high risk of developing delirium. Delirium is the clinical representation of a dysfunctional brain caused by e.g. critical illness. Delirium is characterized by acute disturbances in normal brain function with an altered level of consciousness, inattention, disorganized thinking and often involve hallucinations. Delirium is triggered by an acute medical event, related to drugs or illness.

The standard treatment of this condition is antipsychotics in particular the drug named Haloperidol. However, in recent years it has been questioned whether the treatment should be given as a standard treatment, since evidence have indicated that haloperidol might not have a beneficial effect on delirium and may even lead to increased mortality.

Currently there is no evidence whether the treatment with haloperidol of patients with delirium is beneficial or harmful and there is a vital need of elucidating the role of haloperidol in the treatment of delirium in the Intensive Care Unit.



Inquiry of participation in a medical research project for patients admitted to an intensive care unit
Agents Intervening against Delirium in the Intensive Care Unit (AID-ICU)
15 November 2018, version 2.0

The aim of the project is to determine whether medical treatment of delirium with haloperidol has a beneficial effect in critically ill patients with delirium.

Purpose of the study

The purpose of the study is to assess whether treatment with haloperidol of delirium has a beneficial effect in patients admitted to the intensive care unit.

Status

You were admitted to the intensive care unit and treatment was immediately initiated because your condition required it. In relation to the scientific study you were randomly treated with either haloperidol or placebo (inactive saline) from the time you were diagnosed with delirium until the condition resolved. Two doctors without involvement in the study approved your participation in the study before initiation treatment with the study drugs. Besides the study drugs, you have received the normal treatment for your medical condition.

The study duration is from admission to the intensive care unit until discharge from the intensive care unit, however you will only receive the trial medication if you are diagnosed with delirium.

In addition to the physician in charge of the study, doctors and nurses working in the department contribute by practical implementation of the study.

1 year follow-up

One year after your hospitalisation, a member of the research team will contact you to ask if you would participate in a quality of life survey named EuroQol. This is a brief questionnaire and is of course voluntary.

Discontinuation of the trial

As a participant, you can at any time withdraw from the study without justification. Withdrawal will not affect your relationship with the doctors in the department or your treatment. You will continue to get the treatment that is standard for your medical condition.

Advantages of the experiment

You will not know for sure that participation in the study will be beneficial for you. However, by participating you can help ensuring that we get information telling us whether it is sound to treat delirium with the antipsychotic haloperidol in critically ill patients. Thus, the collected data results in improved treatment of patients in the intensive care unit. Furthermore, since the department is participating in this study, there will be an increased surveillance for delirium among the patients, minimizing the risk of this condition to pass unrecognized. This will ensure early implementation of nonpharmacological interventions against delirium as well as treatment.

Disadvantages of the experiment

There are no disadvantages for you by participating in the study.

Side effects, risks and complications

Haloperidol is a very commonly used and well-known drug. The most frequent reported side effects are usually mild and transient. These include headache, disturbances in movement (trembling, rigid muscles, and involuntary muscle contraction), restlessness and sleep disturbances.



Inquiry of participation in a medical research project for patients admitted to an intensive care unit
Agents Intervening against Delirium in the Intensive Care Unit (AID-ICU)
15 November 2018, version 2.0

Known serious side effects are very rare. These include severe allergic reaction, cardiac arrhythmia, tardive dyskinesia, neuroleptic malignant syndrome, agranulocytosis, pancytopenia, acute hepatic failure and death.

Treatment with saline has no side effects in the amounts administered in this study. When treated with saline you risk not getting a beneficial effect of haloperidol.

Patient compensation

Damage caused by the study drugs is very unlikely in this study. However, if an injury occurs as a result of the study drugs you are covered by the public patient insurance. If you want to complain about anything related to your participation in this study, you can obtain instructions from the research group or from the patient counsellor in the region you live in.

Privacy and confidentiality

All information will be treated confidentially. When reporting results and when publishing the results of the study you will remain anonymous. The Danish Medicines Agency, the Good Clinical Practice monitoring group and the Research group will have access to your entire medical record to ensure that the study is carried out as described in the protocol. From your medical records we will use information about past medical history, surgical procedures during this hospitalization, blood test results, medication, treatment and events in the ICU. Anyone with access to the journal is subject to confidentiality.

Economy

The study is funded by the Innovation Fund Denmark and is unrelated to the pharmaceutical industry. The fund has granted 36 million Danish kroner (4.83 million Euro) for the establishment of a research centre supporting research in intensive care medicine, including the AID-ICU trial. The grant is subject to an external audit. The research group has no financial interest in the study.

Access to study results

When the study is completed we will determine survival and occurrence of side effects among participants. The results will be published in an international scientific journal and on the website of the study (www.cric.nu/aid-icu/).

The duration of the study is estimated to be 2 years, and 1000 patients in Europe will participate.

Contact

We hope that you with this information feel sufficiently informed and able to make a decision about your potential participation. For further information please feel free to contact one of the investigators below.

Sincerely,

Local Principal Investigator:

NAME AND TITLE:
DEPARTMENT:
INSTITUTION:
WORKING ADDRESS:
PHONE:
EMAIL:

Coordinating investigators

Nina Christine Andersen-Ranberg

MD, PhD student
Department of Anaesthesia and Intensive
Care Medicine
Zealand University Hospital, Koege
Denmark

Sponsor

Lone Musaeus Poulsen

MD, head of intensive care
Department of Anaesthesia and Intensive
Care Medicine
Zealand University Hospital, Koege
Denmark