

Hospital-acquired Infection Prevention with Parenteral Omegaven- HIPPO

PROFFESIONAL LEGAL REPRESENTATIVE INFORMATION SHEET

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Introduction

We are inviting you to decide if a patient under your care can take part in a clinical study. We hope this study will improve the care of patients who are admitted to critical care in the future. Patients admitted to critical care often end up having new infections while they are in hospital. These infections can be very serious. Omega-3 fatty acids are fish oil extracts, may be helpful in reducing the number of people that have new infections and also possibly, reduce the length of hospital stay. However, the best dose of omega-3 fatty acids to prevent these new infections has not yet been established. Omegaven is a solution containing omega-3 fatty acids, which is given via a vein. Omegaven contains fish oil and egg, but no pork or beef products or substitutes. Currently, we are identifying which dose of Omegaven tested in this study will have the greatest effect on the immune cells, and is safe, and best tolerated in this specific patient population. This will help us establish a dose that can be given to similar patients in future, and build a case for future studies. Before you decide, it is important to understand why we are doing this research and what it involves. Please take time to read the following information and decide whether or not your patient can take part. You can let us know when you are ready, in a day or two. Please ask us if anything is unclear.

Why are we doing this research?

This is a dose-escalating study, to find the dose of omega-3 fatty acids (provided by Omegaven) that has the greatest beneficial effect on the immune cells, and is safest and well tolerated in this specific patient population. Omega-3 fatty acids in the form of Omegaven are often used as parenteral nutritional support (via a vein) in hospitalised patients in the European Union (the European Society for Clinical Nutrition and Metabolism allows up to 0.2 g fish oil per kilogram bodyweight per day in parenteral nutrition) and Omegaven is routinely used in children with liver disease.

We are studying three doses of Omegaven to be given to adult patients admitted to critical care. The product license is currently for up to 0.2 g Omegaven per kilogram body weight per day, which will be the lowest dose tested. In this trial we will test two further doses of 0.4 and 0.6 g Omegaven per kilogram bodyweight per day. Clinical trials in Europe have already used Omegaven in critically ill patients with sepsis, in cancer patients receiving palliative chemotherapy, and in patients undergoing liver surgery. In an earlier study, critically ill patients were given 0.6 g Omegaven per kilogram bodyweight per day which was well tolerated.

After completion of this trial and identification of a safe dose with beneficial effects on the immune system, we can move this dose forward in a larger study to test whether Omegaven could be given to reduce infections in critical care patients, or help them go home earlier.

Why has my patient been invited?

We have invited you to consider permitting your patient to take part because they are being treated in the critical care ward and are suitable to be included in the study.

Does my patient have to take part?

No. It is up to you to decide whether or not you give permission for your patient to take part in the study. We are asking you to give consent for this patient as they currently do not have the capacity to consent. If you decide that they will have no objections in taking part, we will ask you to sign a Professional Legal Representative Consent Form on their behalf. You are free to withdraw this consent at any time, without giving a reason. If you decide not to give consent for your patient to take part, or later to withdraw, this will not affect the standard of care your patient will receive. We will approach the patient's next of kin as their personal legal representative as soon as it is appropriate to do so, to seek consent. Once the patient regains capacity, we will explain the trial to them and ask for their consent to take part in the study. Patients can also withdraw from the trial at that point.

What will happen to my patient if they take part?

Sometimes we do not know which dose of a drug has the greatest effect. To find out, we need to put people into groups that receive different doses of the drug. The results from the groups are then compared to see if one is better than the other. So, a medical doctor will first confirm the patient's eligibility to take part in the trial, before consent is obtained. Then the patient will be randomised to one group. There are four groups in this study, each with nine patients. Three groups will have patients that will be given different doses of the drug (9 patients receiving 0.2 g/kg/d Omegaven, 9 patients receiving 0.4 g/kg/d Omegaven and 9 patients receiving 0.6 g/kg/day Omegaven) and we will compare the results to those of patients with no Omegaven given at all (9 patients). This means one in four patients might not be receiving Omegaven at all. For these patients, there is no justification reason to give them Omegaven once they are

recovering from their critical illness (after the trial period), so we will not be giving this to them. The groups of patients receiving Omegaven will be completed sequentially. That means, we will only continue to the higher doses after we have considered the safety of the previous dose. If it is not safe to increase the dose, the next nine patients will be given the current dose again.

If your patient is receiving the intervention, we will give Omegaven through their vein for 10 days starting within 48 hours from admission. To make sure Omegaven administration is safe, we will perform blood tests and check the patient's vital signs (looking at the breathing rate, body temperature, blood pressure and heart rate) daily. If these tests and observations are not performed as part of standard care, they will be required under the trial protocol. We will partially use results from standard assessments performed when admitted to the hospital, and will therefore, look at their medical records.

Additionally, blood samples (approximately 40 ml, less than 3 tablespoons) will be collected from them on day 1, 5, 10 and 20 of your patients' hospital stay for research. The blood samples will be obtained, whenever possible, at the same time as the routinely collected blood samples. Laboratory studies will be conducted on the samples to find the effect of the different doses. This will help identify the most effective dose regime to be administered in future patients.

If your patient is not a part of the intervention group, we will also collect blood samples from them on day 1, 5, 10 and 20 from randomisation but they will not be administered Omegaven at all. If you agree, the anonymised blood samples and accompanying anonymised data will also be used for closely related future research studies, which have obtained ethical approval. This consent is optional, and you can decline this, without it affecting your patient's involvement in the HIPPO trial.

In either group, they will still be given all the routine treatment they would receive if not being on the trial. Omegaven is being used separately from normal nutrition, and patients will receive the same type of feed that they would need based on a dietitian's advice, regardless of which group they are in.

We would also like to do a telephone follow-up at 1 month, to find out about their health. Your patient will not need to attend any follow-up appointments in person. We will also check the patient's electronic health records to identify any antibiotic prescriptions and hospital admissions up to the 1 month follow-up. The data we are collecting from your patient will be pseudonymised, so they will not be identifiable from it.

We will also inform their GP that they are participating in this study, so they can add this to their record. We will not share any results of their study tests with them.

What will happen to their samples?

After we have collected their blood sample, we will transport it to the laboratories located at Bart's Health NHS Trust, Queen Mary's University of London and external UK laboratory (OmegaQuant). All samples will be held securely, in access-controlled buildings with access-controlled laboratories with temperature-controlled and -monitored freezers. Access to samples will be to members of the research team only. All samples will be stored in pseudonymised form and therefore, they will not be identifiable from them.

We will use their samples to establish how well they can fight infections, and whether Omegaven made a difference in fighting infections. We will also collect some nutritional and biochemical data from your patient's blood sample, in relation to Omegaven and its metabolism.

At the end of the study, if there is no consent for future research, or if there is no further application to a research ethics committee to perform future research, your patient's samples will be destroyed in accordance with the Human Tissue Act. If consented for samples to be used in further research, then this will be used in accordance with ethical approval obtained and at the end samples will be destroyed in accordance with the Human Tissue Act.

What are the possible risks and benefits of my patient taking part?

We are not expecting any serious side effects to occur during this study. Omegaven contains fish oil, is a licensed drug in the EU, and has been used safely in other groups, e.g. healthy people, people with liver problems, children etc., Omegaven can rarely lead to changes in blood test to do with clotting or liver function. But, changes that affect how doctors and nurses treat patients have not been observed. Additionally, Omegaven can lead to a fishy taste. Some patients have experienced vomiting or had a rash. We would like to collect additional safety information, from closely monitoring your patient during the study period to ensure their safety during Omegaven administration, and to establish that this does not cause diarrhoea or problems from having too much fat. We will monitor levels of fat in the patient's blood daily, just like for any patient who receives feeding through their veins. This is because there is a small chance that too much fat can build up, which can lead to inflammation of some parts of the body, like the pancreas. Because we are used to both giving these types of feed and monitoring patients, we know to stop the Omegaven administration if the fat levels rise outside the acceptable safety limits. In clinical trials in critically ill patients with sepsis, Omegaven administration of up to 0.6 g per kilogram bodyweight was well tolerated. We would only be requiring a small additional volume of blood from your patient, at the same time when tests would be routinely performed on them, on the critical care unit, therefore risks and discomfort would be minimal. Your patient will be contacted by the research team at the end of a 30-day period, starting from their randomisation to enquire about their general health.

We cannot promise the study will help your patient, but the information we get from this research may help to improve health care practices in the future and consequently, help to improve outcomes of future patients who are in the critical care unit.

What are the study restrictions for my patient?

There are no restrictions for your patient with regard to taking part in this study.

If the clinical decision has been made to change the patient to parenteral nutrition (feeding via a vein), they will be withdrawn from the trial.

What will happen if you don't want your patient to carry on with the study?

You can stop your patient taking part at any time.

This will not affect the standard of care that your patient receives. We will stop the intervention (if ongoing). However, we will keep all samples and information collected from your patient up to this point. If you choose to stop their taking part in the study, we would like to continue collecting information about your patient's recovery from the medical records. We may use this data in study reports or final analyses. If you do not want us to collect any further information from your patient's records, tell us and we will stop. Please do get in touch with the study team if you would like to withdraw your patient from the study.

What if I am not happy about the study?

We will not make any changes to the way your patient is cared for in hospital, but, if you have a concern about any part of this study, you should ask to speak with someone from the research team, who will do their best to answer your questions. You may also contact the doctors and nurses who lead the study at this hospital on the telephone number at the bottom of this information sheet. You may also contact the Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care your patient has received, or as an initial point of contact if you have a complaint. Please telephone 0203 594 2040 or email RLHpals.bartshealth@nhs.net. You can also visit PALS by asking at hospital reception. Queen Mary University of London has a "No-Fault Compensation" in place. QMUL has agreed that in the unlikely event your patient experiences harm as a direct result of the procedures your patient received during the study, they will be compensated. These special compensation arrangements apply where an injury is caused to your patient that would not have occurred if they were not in the study. These arrangements do not affect their right to pursue a claim through legal action.

Confidentiality**How will we use information about my patient?**

We will need to use information from your patient's medical records for this research project.

This information will include their:

- NHS and Barts Health medical record number
- Name, DOB, sex, ethnicity
- Contact details
- Medical history and test results

People will use this information to do the research or to check your patient's records to make sure that the research is being done properly. Queen Mary University of London is responsible for looking after the information we collect and will keep this safe and secure. People who do not need to know who you are will not be able to see your patients' name or contact details. Their data will have a code number instead. Your patient's information will be securely processed and stored on behalf of Queen Mary University of London by Swansea University, who coordinates this process and hosts the trial database. Swansea University will be able to see your patient's initials, age, sex, ethnicity and medical history. We will not share this information related to this research project with any other organisation.

International transfers

Your patient's data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your patient took part in the study. We will keep your patient's study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your patient's information is used?

- They can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.
- We need to manage your patient's records in specific ways for the research to be reliable. This means that we won't be able to let them see or change the data we hold about them.
- Your patients have the right to ask us to access, remove, change or delete data we hold about them for the purposes of the study. They can also object to our processing of their data. We might not always be able to do this if it means we cannot use their data to do the research. If so, we will tell them why we cannot do this

Where can you find out more about how your patient's information is used?

You can find out more about how we use your patient's information by:

- Reading our leaflet at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to bartshealth.ccpmg@nhs.net or
- by ringing us on 020 3594 0349.
- by emailing the QMUL sponsor Data Protection Officer - data-protection@qmul.ac.uk

Who is organising and funding the research?

The study is funded by Fresenius Kabi, Germany. Fresenius Kabi will have no part in the day-to-day running of the trial and will have no influence over the results. The study is sponsored by Queen Mary University of London and run by the Critical Care and Perioperative Medicine Research Group at Queen Mary University of London. Your patient's doctor will not receive any payment for including them in the study.

Who has reviewed the study?

All research in the NHS is reviewed by an independent Research Ethics Committee, to protect the interests of the patients who take part. This study has been reviewed and granted a favourable opinion by the London-Fulham Research Ethics Committee (**Date**), and the Medicines and Healthcare products Regulatory Agency (MHRA, **Date**). The local NHS Research and Development department has agreed that the study can be conducted in this hospital.

How do I find out about the results of the study?

The results of the study will be published online and made available through Queen Mary University of London and Barts Health NHS Trust research reports.

Thank You

Thank you for considering giving permission for your patient to take part in this study and for reading this information sheet, which is yours to keep. If you decide your patient can take part in the study, you will also be given a copy of the Professional Legal Representative Consent Form. Please note, we will also inform the patient that you consented for their involvement in this study on their behalf.

The study doctor is:

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The research/specialist nurse is:

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