

Hospital-acquired Infection Prevention with Parenteral Omegaven- HIPPO

DELAYED PATIENT INFORMATION SHEET

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Introduction

We are inviting you to decide if you would like to continue taking 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, which are fish oil extracts, may be helpful in reducing the number of people that have new infections and 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 you would like to continue taking part.

You have already been enrolled in this study. Your legal representative (the doctor treating you), and potentially your personal representative (a family member or close friend), have given consent for you to be included. When you were admitted to the adult critical care unit, you were very ill and therefore, we could not talk to you to consent to the trial yourself. They did this after considering the information provided to them in a similar information sheet and considering if you would have liked to be part of a research study and if you would have given consent. Therefore, you might have already received the study intervention (Omegaven), if you were in one of the intervention groups, and we have already taken a blood sample for research. We would now like to discuss this trial with you, explain the next steps to you and obtain your consent to remain in the study.

Talk to your friends and family about the study if you wish. You can let us know when you are ready, in a day or two. Please let us or know if anything is unclear. You can also contact your

study doctor, if you have any medical questions. The other option is to withdraw from the study. In this case no further intervention is given, and no further blood samples are collected. Further detailed information about withdrawal can be found in the respective section below.

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 when food is given through the veins in hospitalised patients in the European Union.

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 bodyweight 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 am I invited?

You were enrolled in the study because you have been admitted to our critical care unit and the doctors and nurses treating you have identified you to be considered suitable to be included in the study. We have already obtained your legal representative's consent and would now like to discuss this further with you.

Do I have to take part?

No. It is up to you to decide whether or not you think you would like to remain in the study.

If you are happy to remain in this study, we will ask you to sign a Consent Form. We will keep you fully informed during the study so you can let us know if you have any concerns. You are free to withdraw your consent, or the consent given by your legal representative(s) at any time, without giving a reason. If you decide that you want to withdraw from the study, this will not affect the standard of care you will receive. If you are unsure about remaining in the study, you may seek independent advice.

What will happen to me if I 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 has first confirmed your eligibility to take part in the trial. Then you were 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 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 one after the other so that we can make sure that we 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 group of patients will be given the current dose again.

If you are receiving the intervention, we give Omegaven through your vein for 10 days starting within 48 hours from admission. If you were in this group, this has most likely already started for you. To make sure Omegaven administration is safe, we perform blood tests and check your 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 partially use results from standard assessments performed when admitted to the hospital, and therefore, look at your medical records. Additionally, blood samples (approximately 40 ml, less than 3 tablespoons) are collected from you on day 1, 5, 10 and 20 of your hospital stay. The blood samples will be obtained, whenever possible, at the same time as your 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 you are not a part of the intervention group, we are also collecting blood samples from you on day 1, 5, 10 and 20 from randomisation but you 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 involvement in the HIPPO trial.

In either group, you are still be given all the routine treatment you would receive if not being on the trial. Omegaven is being used separately from normal nutrition, and you receive the same type of feed that you would need based on a dietitian's advice, regardless of which group you are in. We would also like to do a telephone follow-up at 1 month, to find out about your health.

You will not need to attend any follow-up appointments in person. We are also checking your electronic health record to identify any antibiotic prescriptions and hospital admissions up to the 1 month follow-up. The data we are collecting from you will be pseudonymised, so you will not be identifiable from it.

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

What will happen to my samples?

After we have collected your blood sample, we will transport it to the laboratories located at Bart's Health NHS Trust, Queen Mary University of London and to an 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, you will not be identifiable from them.

We will use your samples to establish how well you can fight infections, and whether Omegaven made a difference in fighting infections. We will also collect some nutritional and biochemical data from your 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 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 taking part in the study?

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 tests 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 you during the study period to ensure your safety during Omegaven administration, and to establish that this does not cause diarrhoea or problems from having too much fat. We are monitoring levels of fat in your 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 you, at the same time when tests would be routinely performed on you, on the critical care unit, therefore risks and discomfort would be minimal. You will be contacted by the research team at the end of a 30-day period, starting from your randomisation, to enquire about your general health.

We cannot promise the study will help you, 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 can I do and what should I avoid?

There are no restrictions for you with regard to taking part in this study. If the clinical decision has been made to change you to parenteral nutrition (feeding via a vein), you will be withdrawn from the trial.

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

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

What if I am not happy about taking part in the study?

We will not make any changes to the way you are 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 Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care you have 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 you experience harm as a direct result of the procedures you received during the study, you will be compensated. These special compensation arrangements apply

where an injury is caused to you that would not have occurred if you were not in the study. These arrangements do not affect your right to pursue a claim through legal action.

What if new information becomes available?

The research doctor will provide you with details. If you decide that you do not want to continue with the study, then please inform the study team.

Confidentiality

How will we use information about you?

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

This information will include:

- 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 records to make sure that the research is being done properly. Queen Mary University of London is responsible for looking after your information we collect and will keep this safe and secure by storing the information in a password-controlled database. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Your 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 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 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 you took part in the study. We will keep your 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 information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have and use it for analyses. This includes the results obtained from the tests done on the sample collected before you withdraw from the study.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

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

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

- reading our leaflet: 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 0351.
- by emailing the QMUL 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 doctor will not receive any payment for including you 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 your continued participation in this study and for reading this information sheet, which is yours to keep. If you decide to continue to take part in the study, you will also be given a copy of the Informed Consent Form.

Your study doctor is:	Contact phone number:
Prof Zudin Puthucheary	020 3594 0351
Your research/specialist nurse is:	Contact phone number:
Name:	020 3594 0351