

Hospital-acquired Infection Prevention with Parenteral Omegaven- HIPPO

PERSONAL LEGAL REPRESENTATIVE INFORMATION SHEET

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Introduction

We are inviting you to decide if your relative or friend would like to 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 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 on behalf of your relative or friend, 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 relative or friend would like to take part.

It is possible that your friend or relative has already been enrolled in the study by the consultant in charge of their care, acting as their professional legal representative, given the drug if they are in one of the intervention groups and had blood samples collected for the study. This is because their doctor may have consented on their behalf within 48 hours of their admission, while they were incapacitated, in this case please read the information carefully to decide whether you think your friend or relative would like to continue being part of the trial. Their doctor or research nurse can provide further information about your friend's or relative's group

allocation. You can withdraw their enrolment in the trial without your friend's or relative's care being affected.

Talk to their other friends or family about the study and decide if your relative or friend would wish to take part. You can let us know when ready, in a day or two. Please ask us if anything is unclear. Once your friend or relative regains capacity to decide for themselves, we will also ask for their consent to be part of the study.

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 to test whether Omegaven could be given to reduce infections in critical care patients, or help them go home earlier.

Why has my relative/ friend been invited?

We have invited your relative or friend to consider taking part in this study because they have been admitted to our critical care unit and the doctors and nurses treating your relative or friend have identified them to be considered suitable to be included in the study.

Does my relative/ friend have to take part?

No. It is up to you to decide whether or not you think your relative or friend would like to be involved in the study. We are asking you to consider consenting to the study on behalf of your relative or friend as they currently do not have the capacity to consent. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide that in your opinion, your relative or friend will be happy to take part in this study, we will ask you to sign a Personal Legal Representative Consent Form, so they can stay enrolled in the trial. 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 relative or friend at any time, without giving a reason. If you decide that your relative or friend will not want to take part, or later to withdraw them from the study, this will not affect the standard of care your relative or friend will receive. If you are unsure about taking the role of Personal Legal Representative you may seek independent advice.

We will understand if you do not want to take on this responsibility. We will ask your relative or friend to consent to taking part in the study as soon as they are able to do so. They also have the option to withdraw from the trial at that point.

What will happen to my relative/ friend 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 your friend or relative's eligibility to take part in the trial. Then they 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 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 your friend or relative 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 your relative or friend on day 1, 5, 10 and 20 of their hospital stay for research. The blood

samples will be obtained, whenever possible, at the same time as their 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 they are not a part of the intervention group, we will also collect their blood samples on day 1, 5, 10 and 20 from randomisation but they will not be administered Omagaven 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 friend or relative'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 they 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. They 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 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 the study tests with them.

What will happen to the samples collected from my friend or relative?

After we have collected your relative or friend's blood sample, we will transport it to the laboratories located at Bart's Health NHS Trust, Queen Marys University of London and 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 stores in pseudonymised form and therefore, your relative or friend will not be identifiable from them.

We will use these blood samples to establish how well your relative or friend can fight infections, and whether Omegaven made a difference in fighting infections. We will also collect some nutritional and biochemical data from your relative or friend'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 relative or friends blood 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 relative/ friend 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 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 friend or relative 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 have only been/would only be requiring a small additional volume of blood from your relative or friend, 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 relative or friend will be contacted by the research team at the end of a roughly 30-day period, starting from their admission, to enquire about your relative or friend's general health.

We cannot promise the study will help your relative or friend, 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 my relative or friend do and what should they avoid?

There are no restrictions for your relative or friend 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 friend or relative to carry on with the study?

You can withdraw your friend or relative from the study at any time. This will not affect the standard of care that your relative or friend receives. We will stop the intervention (if ongoing). However, we will keep all samples and information collected from your friend/relative up to this

point. If you choose to stop them taking part in the study, we will continue collecting information about your friend or relative'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 their records, tell us and we will stop. Please do get in touch with the study team if you would like to withdraw your friend or relative from the study.

Once your friend or relative regains capacity to make decisions for themselves again, we will provide them with an information sheet and ask them to provide consent for their participation in the trial. They are free to decline participation without their medical care being affected. They can also withdraw at a later timepoint in the same manner.

What if I am not happy about my relative/ friend taking part in the study?

We will not make any changes to the way your relative or friend 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 Patient Advisory Liaison Service (PALS) if you have any concerns regarding the care your relative or friend 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 relative or friend experiences harm as a direct result of the procedures they received during the study, they will be compensated. These special compensation arrangements apply where an injury is caused to your relative or friend 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.

What if new information becomes available?

The research doctor will provide you with details. If you think that at this point your relative or friend would not want to continue with the study, then please inform the study team.

Confidentiality

How will we use information about your relative or friend?

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

This information will include:

- NHS and Barts Health medical record number

- Name, DOB, sex
- Contact details
- Medical history and test results

People will use this information to do the research or to check your relative or friend's records to make sure that the research is being done properly. Queen Mary University of London is responsible for looking after your relative or friend's information we collect and will keep this safe and secure. People who do not need to know who the participants are will not be able to see your relative or friend's name or contact details. Your relative or friend's data will have a code number instead. Their 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 friend or relative'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 relative or friend'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 relative or friend took part in the study. We will keep your relative or friend'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 relative or friend's information is used?

- You, on behalf of your relative or friend, can request they stop being part of the study at any time, without giving a reason, but we will keep information about your relative or friend that we already have and use it for analyses. This includes the results obtained from the tests done on the sample collected before your relative or friend withdrew from the study.
- We need to manage your relative or friend's records in specific ways for the research to be reliable. This means that we won't be able to let your relative or friend see or change the data we hold about your relative or friend.
- Your relative/friend has 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 you why we cannot do this

Where can you find out more about how your relative or friend's information is used?

You can find out more about how we use your relative or friend'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 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 relative or friends' doctor will not receive any payment for including your relative or friend 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 deciding if your relative or friend can take part in this study and for reading this information sheet, which is yours to keep. If you decide your relative or friend can take part in the study, you will also be given a copy of the Personal Legal Representative consent form.

Your relative or friend's study doctor is:

Prof Zudin Puthucheary

Contact phone number:

020 3594 0351

Your relative or friend's research/specialist

Contact phone number:

nurse is:

Name _____

020 3594 0351