

## Participant Information Sheet

Study Title: **EDMONd – A feasibility study of Elemental Diet as an alternative to parenteral nutrition for patients with inoperable Malignant bowel Obstruction**

IRAS project ID:  
REC reference:  
Sponsor

215192  
16/LO/2079  
The Royal Surrey County Hospital

We would like to invite you to take part in our research study at the Royal Surrey County Hospital. Before you decide, we would like you to understand why the research is being done and what it would mean for you. **One of our team will go through the information sheet with you and answer any questions you have.** Talk to others if you wish.

### What is the purpose of the study?

Bowel blockage is a common complication in patients with ovarian, peritoneal and bowel cancer as these cancers can grow on the bowel surface. Unfortunately this type of blockage often occurs on many parts of the bowel and therefore surgery is frequently not possible and chemotherapy is often not effective.

If this occurs, eating and drinking often leads to abdominal pain and vomiting and feeling very unwell. If the blockage is complete, eating is not possible. If the blockage is partial (the most common occurrence) then patients are often able to swallow small amounts of liquid.

Currently the only method of feeding and providing nutrition is to give food through the veins through a long line called a PICC line. This is called parenteral nutrition (PN). PN is a complex process that can only be set up in specialist centres and requires extensive training. It often means a long stay in hospital before patients are allowed to go home. There is also a risk of infection from the PICC line.

Elemental diet is a type of a drink that is already digested so that the body does not need to do any work. It contains energy, broken-down proteins and vitamins and minerals. Elemental drinks are almost totally absorbed in the upper part of the bowel and therefore could be absorbed even in patients who have bowel blockage lower down in the gut.

We want to investigate if an elemental diet can offer an alternative to PN, and can be used as an acceptable form of nutrition in hospital and at home. We want to see if patients like the drinks, and if symptoms of pain and vomiting are not made worse. We also want to establish if this form of nutrition improves the quality of life of patients at this difficult time. This study has been reviewed by patients and they have helped in the design of this study.

Please note this is a clinical trial and the benefits to you are not yet known.

**Why have I been chosen?**

You have been invited to take part in this study because you have been diagnosed with bowel obstruction (blockage) caused by cancer and the surgeons do not feel that the blockage can be relieved by surgery.

**Do I have to take part?**

It is up to you to decide to join the study. We will explain how the study works and go through this information sheet with you.

If you agree to take part, we will then ask you to sign a copy of the consent form.

If you do decide to take part you will be given this information sheet to keep and a copy of your signed consent form.

You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. You should only volunteer if you have the time to complete the whole study.

**What will happen to me if I take part?**

Your involvement in the study would only last for 2 weeks. During this time, you will be asked to keep in contact with the research nurse at your hospital and fill in a food and elemental diet diary as well as health and quality of life questionnaire. Each of the assessments will last around 20-30 minutes. If you are hospitalised you will be requested to do that in the hospital, if you are at home a nurse will call you at home, and we will ask you to post the questionnaires to us. You will be given a study schedule.

We may also ask you whether you would agree to participate in an additional interview with the research nurse and have your answers digitally recorded during this time. This part of the study is additional and you may wish to opt out of it.

**Benefits and Payments**

There will be no payment to you. We hope that the results of this study will improve the care for patients in the future.

**What will I have to do?**

You will be asked to complete a number of questionnaires and a diet diary if you go ahead with the study.

*Diet diary*

During the study you will be given detailed instructions of how to take the elemental drinks. The dietitian will see you before you leave hospital and explain how many cartons of elemental you need to drink on each day. We will ask you to fill in a diary on a daily basis for the 2 weeks you take part in the study.

In the diary you will be asked to record which flavours you like best, and how many cartons of elemental you drink each day. You will also be asked to write down any other drinks you have each day for the 2 weeks that you are participating in the study.

*Questionnaires*

You will be asked to fill in 2 questionnaires. The first will have questions on your symptoms such as pain, nausea and vomiting. The second is a quality of life questionnaire.

During the study, if you are prescribed any new medications (including creams, ointments, inhalers) or if you buy any non-prescription medications (including herbal remedies), from the pharmacy, supermarket or health food shop, you must report the name of the drug(s)/herbal preparation(s), the dose, and the dates and duration of treatment at your next contact with the research nurse.

Once you are discharged home (if this happens within the two weeks on the study) the research nurse will contact you at home by telephone and will ask for the completed diary and the questionnaires to be sent to us (using a pre-paid envelope).

You will be given an emergency contact card to carry when you are not at the hospital and this will have the details of the study on it and an emergency contact number. You should carry this with you at all times during the study in case of emergency.

**What are the alternatives for diagnosis or treatment?**

If you decide not to take part in this study, you will still be given advice on how to manage your nutrition by your oncologist and dietitian.

**What are the possible disadvantages and risks of taking part?**

An elemental diet has not been shown to cause harm and is a safe form of nutrition. However there may not be benefit from using the drinks in the cancer setting. We do not anticipate that an elemental diet will prevent your usual cancer care from going ahead.

**What are the possible side effects of any treatment received when taking part?**

An elemental diet may cause some nausea and vomiting especially if the blockage in the bowel worsens once you are participating in the study. This may also lead to abdominal pain.

Elemental drinks have been used for many years in patients with bowel inflammation and it is important that it is introduced slowly or it may also cause some loose bowel motions. You will be given detailed instructions on how to start using the products.

**What are the possible benefits to health from taking part?**

We cannot promise the study will help you but the information we get from this study may help improve the treatment of other people with this condition.

**What happens when the research study stops?**

At the end of the 2 week study period, your study doctor will discuss continuing with the elemental diet if this is appropriate. If you blockage improves your dietitian will give you advice on gradually re-introducing solid foods.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions

**Will my taking part in the study be kept confidential?**

Yes. Your details will be held in complete confidence in accordance with the Data Protection Act (1998) and we will follow an ethical and legal practice. When you are

recruited to the study, you will be given a unique reference number (study number). This number will be used to identify your data instead of your name or personal information. Information on your experience on the study and questionnaires you fill during the study will be stored on secure NHS and University of Surrey computers. Only the clinical staff will have access to your personal data.

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

You may decide to withdraw from the study at any time. This will not affect the standard of care you receive. Your study doctor will discuss arrangements for your continued care with you.

Information that has already been collected from you will continue to be used for the purposes of the study. It will be up to you to decide if data from your final visit can be used or not.

**Will my General Practitioner (GP) be informed?**

Yes, it is routine practice to inform your GP that you are taking part in a study and to check if there is any reason why you would not be suitable for the study. Your GP will be provided with details of the study and, with your consent, may also be sent any clinically significant screening results. We may also ask your GP to send us information about your medical history. This is one of the things you agree to when you sign the consent form.

**Who is organising and funding the research?**

This research study is being sponsored by Royal Surrey County Hospital and funded by Target Ovarian Cancer Charity.

**Who has reviewed the study?**

This study has been looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. You will be given a copy of this information sheet and the signed consent form to take home with you.

**Further information and contact details.**

If you have any questions about this study, please contact:

Dr Agnieszka Michael on 01483 571122 ext 2064 (during normal office hours)

Emergency acute oncology hotline on 01483 571122 and ask for the oncology doctor on call (emergency contact)