EMT2: A randomised placebo-controlled phase III trial of the effect of the omega-3 fatty acid eicosapentaenoic acid (EPA) on colorectal cancer recurrence and survival after surgery for resectable liver metastasis

IRAS ID: 199321

We wanted to contact you to make sure you understand how we use the information we collect about you in the EMT2 Trial. This is because new data protection laws (called the EU General Data Protection Regulation [GDPR] and UK Data Protection Act 2018) came into force on 25th May 2018. These laws mean that you must have clear information about how information about you is collected and used.

This letter provides some more information about how the data we collect from you is used, in addition to the patient information sheet you were given before you joined the trial.

General information

University of Leeds is the sponsor for this study based in the United Kingdom. The University of Leeds of Leeds has asked the Clinical Trials Research Unit **(CTRU)** at the University of Leeds to run the EMT2 study on their behalf.

CTRU will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about you for **at least 15 years** after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://ctru.leeds.ac.uk/privacy/.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer can be contacted using the following details:

- Email: DPO@leeds.ac.uk
- General postal address: University of Leeds, Leeds LS2 9JT, UK
- Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT
- Telephone number: +44 (0)113 243 1751

How your information is used

Your hospital will collect information from you and your medical records for this research study in accordance with our instructions.

Your hospital will use your **name, date of birth and NHS number** to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. **If you have agreed to have your study medication delivered via a courier, your address will be used for invoicing purposes only**.

Individuals from the **CTRU** and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your hospital will pass these details to **CTRU** along with the information collected from you and your medical records. The only people in **CTRU** who will have access to information that identifies you will be people who audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name.

The **CTRU** will collect information about you for this research study from your hospital. This information will include **your name, date of birth NHS number** and health information, which is regarded as a special category of information. We will use this information to **run the trial and analyse the results**.

Your hospital will keep identifiable information about you from this study for **at least 15 years** after the study has finished.

Using your information for further research

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with

the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

We would like to take this opportunity to thank you again for taking the time to read this information, and for your participation in the trial.

On behalf of the EMT2 Trial team,

Professor Mark Hull

EMT2 Chief Investigator