

MESSAGE TO EMT2 TRIAL PARTICIPANTS FROM THE CHIEF INVESTIGATOR, PROFESSOR MARK HULL Dear Participant

I do hope you are keeping safe and well during the current national disruption.

I know that you will be worried about the consequences of the COVID-19 pandemic for your health, as well as that of your family and friends. I am sure that you will have thought about the EMT2 trial and whether the trial capsules could affect your risk of and outcome from infection. Colleagues and I have also considered how disruption to the trial from staff illness and self-isolation and redeployment might affect the conduct of the trial.

Below I have tried to answer some of the main questions you may be asking. If you have other questions or want more detail, you must not hesitate to contact your local research team using the contact number that you were given at the start of the trial. It is important to re-iterate that you are free to stop the trial medication or leave the trial entirely at any time without any effect on your clinical care.

DOES THE EPA IN THE ACTIVE CAPSULES AFFECT COVID-19 RISK?

We don't think so. The EPA you are taking in the EMT2 trial is a natural omega-3 fatty acid substance, but we are using it at a much higher dose than you would get in your normal diet. There is no suggestion that omega-3 supplement use increases the risk of getting a viral infection or the course of an infection. There was a large international trial of the same dose and type of EPA that is being used in EMT2 called REDUCE-IT. The REDUCE-IT trial showed that there was no difference in the small number of patients who got influenza or other upper respiratory infections between patients receiving EPA or the dummy placebo.

WHAT HAPPENS IF THE NHS IS AFFECTED BY THE COVID-19 EPIDEMIC AND RESEARCH STAFF ARE NOT AVAILABLE TO MONITOR ME?

There are 10 NHS hospital sites with patients in EMT2 across England. Each hospital is planning for how it will cope with COVID-19 and one aspect is to understand the effect on research trials if nurses and doctors become ill or have to go and help care for patients elsewhere in the hospital. Each hospital will make a decision whether it can safely monitor and support patients in all its trials including EMT2. Hospitals will probably stop new patient recruitment to trials so that they can look after patients already in trials. The excellent safety record of EPA and the fact that trial visits are infrequent and can be done by phone mean that EMT2 is less likely to be affected than other studies. If there is any problem running the trial, you will be contacted by your local hospital.

As you are aware the EMT2 trial is critical to improving the success of the future treatment received by patients, similar to yourselves. Your help in the trial is essential and your involvement will ensure we have the information required to hopefully help future patients.

The team appreciate your input, and are extremely grateful for your continued support in the trial.

Yours sincerely

Professor Mark Hull (Consultant Gastroenterologist, Leeds and Lead Investigator of EMT2)

EMT2 patient letter about COVID-19 version 1.0 dated 19th March 2020