

EMT2: Key Facts

- This is a major clinical study which involves a large number of volunteers, like you, to hopefully find an improved method of treating liver metastasis (spread of cancer) following bowel (colon) cancer.
- Participation of volunteers such as yourself is essential for the success of this clinical trial, although there may or may not be any direct benefit to you.
- Your standard of treatment and care will not be affected by either volunteering or not taking part in the trial. Always remember that you can withdraw from the trial at any point, without giving a reason.
- The purpose of the EMT2 study is to find out if there is a benefit in taking EPA capsules before and after liver surgery. Although there is some indication that EPA will work, we need to run a trial as we don't know for sure.
- EPA is one of the main fatty acids found naturally in fish. The capsules used in the trial are pure EPA and a higher dosage and quality than anything available on the high street. EPA is derived from fish and the capsule contains gelatin from an animal source so the trial is not suitable for a Vegetarian. No other omega-3 fatty acid supplements should be taken during the trial.
- Volunteers will be randomly selected (by a computer) to receive either the EPA or a dummy (placebo) capsule. Neither you nor your doctor will choose or know what capsules you are taking during the course of the trial, unless there are medical reasons or problems. This is the best way to finding out if EPA works in an unbiased way.
- You will start treatment before liver surgery and will continue with the treatment for between 2 and 4 years dependent on when you join. This treatment includes taking 4 capsules every day, at times to suit you.
- When taking EPA a few participants may experience some mild side effects relating to their digestive system, but these often can be minimised if the capsules are taken at meal times.
- There will be regular contact by either telephone or study appointments (maybe 5-10), which will link to your standard care appointments, wherever possible. If transport is a problem then telephone follow-up can be done and capsules posted. These visits will include a review of your progress, a health questionnaire, a prescription for new capsules and, for some participants, a blood test.
- Because this is a clinical trial, special consideration may need to be offered for females who are pregnant or become pregnant. Also male participants whose partner becomes pregnant may also need consideration.
- Confidentiality during the trial is important, and the information collected about you will be handled in accordance with the consent form and the Data Protection Act 2018.