

NET-02: A multi-centre, randomised, parallel group, open-label, phase II, single-stage selection trial of liposomal irinotecan (nal-IRI) and 5-fluorouracil (5-FU)/folinic acid or docetaxel as second-line therapy in patients with progressive poorly differentiated extra-pulmonary neuroendocrine carcinoma (NEC)

Chief Investigator: Dr Mairéad McNamara

There is no established treatment option for patients with a diagnosis of poorly differentiated (faster growing) neuroendocrine carcinoma (NEC) that started outside the lung, that has spread, and whose disease has not responded to treatment with a chemotherapy combination containing a platinum drug. In the NET-02 trial, half of the patients will receive a novel drug combination, that has been reported to improve survival in patients with pancreas cancer (that has spread and cannot be cured), called liposomal irinotecan and 5-fluorouracil, together with a vitamin-like substance called folinic acid **or** docetaxel (which is a treatment option currently available for patients with a diagnosis of NEC from the lung, and is used in other cancers such as breast cancer and lung cancer).

The goal of NET-02 will be to determine if one of the treatment options delays growth and/or spread (progression) of the disease, more than the other. Patients will also be asked to consent to donating some blood samples during the study and a sample of tissue that was taken at the time they were diagnosed. Samples will be used to find out what gene patterns may increase the risk of developing NEC, and to determine the relevance of these changes in terms of life-span, and whether they are linked to a better response or not to treatment. A certain number of patients may also consent to allowing their blood samples to be used to develop an animal model of NEC, where there would be the potential to investigate new treatment options, and so develop a novel clinical trial in an effort to improve survival for patients with this devastating disease.

This study will be open in approximately 16 centres around the United Kingdom and will be co-ordinated through The Christie NHS Foundation Trust in Manchester, the University of Manchester and the Leeds Clinical Trials unit.

If you have any questions please call our nurse helpline on 0800 434 6476