aRTisAN: A Phase II Assessment of the Safety and Efficacy of TheraSphere® Selective Internal Radiation Therapy (SIRT) in the treatment of Metastatic (Liver) Neuroendocrine Tumours (NETs)

Chief Investigator: Dr Rohini Sharma, Imperial College London

Research studies, also called clinical trials, are performed to learn more about the effectiveness and safety of medicines and medical devices. The health authorities require medicines and medical devices to be tested in clinical studies before granting approval for use.
This clinical trial has been approved by an independent ethics committee named: London - Bloomsbury Research Ethics Committee. This committee consists of a group of independent people that will review the study related documents to ensure the rights, safety and well-being of patients are protected.

The study will include 24 patients with a neuroendocrine tumour that has spread to the liver, have been on somatostatin analogues for at least 3months, and have liver tumours that cannot be removed by surgery.
The study is being arranged, organised by Imperial College, London also referred to as the 'sponsor' of the study, and financed by Biocompatibles UK Ltd, Chapman House, Farnham Business Park, Weydon Lane, Farnham, Surrey, GU9 8QL, United Kingdom.

The purpose of this research study is to examine whether adding treatment with TheraSphere with the current standard treatment for NETs with liver metastases (somatostatin analogues) slows or stops the growth of liver tumors without experiencing a significant increase in number or severity of side effects.
There are no other treatments being evaluated in this study.

TheraSphere is a medical device containing yttrium-90 (Y-90), a radioactive material that has been used previously in the treatment of liver tumors. Y-90 is incorporated into very tiny glass beads (TheraSphere), and is injected into the liver through the blood vessels supplying blood to the liver. The goal of treatment with TheraSphere is to allow a large dose of radiation to be delivered directly to the tumor with less risk of toxic effects from radiation to other parts of the body or to healthy parts of the liver compared with currently available treatments.
In Europe, Canada and America, TheraSphere is approved for treatment of tumours in the liver.

As with all studies there are inclusion and exclusion criteria - if you would like further information please email : nikie@nc-uk.org

You may also contact the Principal Investigator, Dr Rohini Sharma, at Hammersmith Hospital to answer any questions you might have about the study.