

NET01: A randomised phase II study comparing capecitabine plus streptozocin with or without cisplatin chemotherapy as treatment for unresectable or metastatic neuroendocrine tumours

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On behalf of UKINETS

This phase II trial randomises patients with unresectable or metastatic gastroenteropancreatic neuroendocrine tumours to receive one of two combination chemotherapy regimens.

84 eligible patients will be randomised to receive either capecitabine plus streptozocin ('cap-strep'), or capecitabine plus streptozocin plus cisplatin ('cap-cist'). Treatment will continue for 18 weeks, or until disease progression.

The results of this randomised phase II study will be used as a basis from which to design a first UK phase III trial of systemic therapy for NETs, supported by the UKINETS multidisciplinary group and the NCRI Upper GI clinical studies group.

OBJECTIVES

Primary Objective:

- To determine the objective response rates of the 'cap-strep' and 'cap-cist' regimens.

Secondary objectives include:

- Overall response rate, to include both objective and biochemical responses
- Functional response
- Toxicity of both combination regimens
- Biomarkers predictive of response and outcome