A randomised phase II study comparing capecitabine plus streptozocin with or without cisplatin in the treatment of unresectable or metastatic gastroentero-neuroendocrine tumours of the foregut, pancreatic neuroendocrine tumours and neuroendocrine tumours of unknown primary site

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/12/2005		Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/02/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
19/10/2018	Cancer			

Plain English summary of protocol

http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chemotherapy-for-neuroendocrine-tumours-that-have-spread-or-cant-be-removed-with-an-operation

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-005202-71

ClinicalTrials.gov (NCT)

NCT00602082

Protocol serial number

N/A

Study information

Scientific Title

A randomised phase II study comparing capecitabine plus streptozocin with or without cisplatin in the treatment of unresectable or metastatic gastroentero-neuroendocrine tumours of the foregut, pancreatic neuroendocrine tumours and neuroendocrine tumours of unknown primary site

Acronym

NET 01

Study objectives

What are the objective response rates of two chemotherapy regimens being tested in patients with unresectable or metastatic NeuroEndocrine Tumours (NET) originating from the stomach, duodenum, pancreas or from an unknown primary site?

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West MREC on 23/08/2005 (ref: 05/MRE06/32)

Study design

Interventional, randomised controlled trial, phase II trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neuroendocrine tumour

Interventions

Patients will be randomised to one of two groups:

- 1. Streptozocin (Zanosar) injection on the first day of every three week cycle
- 2. Streptozocin (Zanosar) and cisplatin injections on the first day of each three week cycle

Each patient will have up to six cycles of chemotherapy treatment over 18 weeks. One treatment cycle will last three weeks (21 days). Both groups will also be taking capecitabine (Xeloda) tablets continuously, twice a day, for 18 weeks. Patients will be asked to fill in a quality of life questionnaire before they start treatment, every nine weeks during the treatment and 12 weeks after the last treatment. Patients will also have CT and MRI scans every three cycles (nine weeks) while they are having the treatment.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Streptozocin, cisplatin, capecitabine

Primary outcome(s)

Objective response rate.

Key secondary outcome(s))

- 1. Overall response rate, to include both objective and biochemical responses
- 2. Functional response
- 3. Toxicity of both combination regimens
- 4. To identify the optimal drug doses in each regimen to be recommended for a subsequent phase III trial
- 5. Progression-free survival
- 6. Overall survival
- 7. Quality of life
- 8. Molecular markers predictive of response to chemotherapy

Completion date

31/05/2009

Eligibility

Key inclusion criteria

- 1. Patients with histological confirmation of resectable, advanced and/or metastatic:
- 1.1. Gastroentero-neuroendocrine tumour of the foregut
- 1.2. Pancreatic neuroendocrine tumour
- 1.3. Neuroendocrine tumour of unknown primary source
- 2. Measureable disease, defined by the presence of at least one lesion which can be accurately measured in at least one dimension with longest diameter more than 20 mm using conventional Computed Tomography (CT) scanning, or more than 10 mm with spiral CT or Magnetic Resonance Imaging (MRI)
- 3. No prior or concomitant chemotherapy or immunotherapy administered for this condition
- 4. Life expectancy more than 12 weeks
- 5. Performance status zero, one or two (Eastern Cooperative Oncology Group [ECOG] performance scale)
- 6. Aged over 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Bronchial NETs
- 2. No previous systemic chemotherapy or chemotherapy administered as part of a chemoembolisation regimen is allowed. Prior interferon is allowed. In this case, the time interval between the last dose of interferon and the date of commencing chemotherapy within this trial should be at least three weeks
- 3. Any previous investigational agent within the last four weeks. Patients may have previously received somatostatin analogues. Patients on somatostatin analogues are eligible to enter the study if their symptoms are no longer controlled by this treatment or there is documented measurable disease progression on serial CT scans performed up to six months apart, as defined by Response Evaluation Criteria In Solid Tumors (RECIST) criteria. At the time of trial entry, it is acceptable for the patient to continue their somatostatin analogue therapy or to stop it, depending on individual circumstances
- 4. Palliative radiotherapy involving any of the lesion(s) being used to measure disease. Palliative radiotherapy to regions not involved in measurement of disease is permitted.
- 5. Any other serious or uncontrolled illness, which in the opinion of the investigator, makes it undesirable for the patient to enter the trial
- 6. Any medical or psychiatric condition which would influence the ability to provide informed consent
- 7. Pregnant or lactating women

Date of first enrolment

01/06/2005

Date of final enrolment

31/05/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oncology Centre

Cambridge United Kingdom CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

https://ror.org/04v54gj93

Funder(s)

Funder type

University/education

Funder Name

Addenbrookes Hospital Oncology Centre (UK) - costs of trial administration

Funder Name

University of Glasgow Pathology Department (UK) - pathological study costs

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014		Yes	No
Plain English results				No	Yes