ISRCTN35124268 https://doi.org/10.1186/ISRCTN35124268

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
09/12/2005

Recruitment status
No longer recruiting

Registration date
06/02/2006

Overall study status
Completed

Last Edited
19/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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Additional identifiers

EudraCT/CTIS number
2004-005202-71

IRAS number

ClinicalTrials.gov number
NCT00602082

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
Objective response rate.

Secondary outcome measures
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

Overall study start date
01/06/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
84; 42 in each arm

Key exclusion criteria
1. Bronchial NETs
2. No previous systemic chemotherapy or chemotherapy administered as part of a chemo-embolisation 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
England

United Kingdom

Study participating centre
Oncology Centre
Cambridge
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Results article	results	01/03/2014		Yes	No