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Randomised phase III study of docetaxel versus active symptom control in patients with relapsed gastric adenocarcinoma

Submission date 19/09/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/11/2007	**Overall study status** Completed	
Last Edited 19/03/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-docetaxel-chemotherapy-for-advanced-cancer-of-the-stomach-the-oesophagus-or-the-junction-of-the-stomach-and-oesophagus

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00978549

Clinical Trials Information System (CTIS)
2006-005046-37

Protocol serial number

C21276/A7737

Study information

Scientific Title
Randomised phase III study of docetaxel versus active symptom control in patients with relapsed gastric adenocarcinoma

Acronym
COUGAR-02

Study objectives
To establish the role of chemotherapy with docetaxel as second line therapy for advanced gastric cancer in terms of overall survival.

On 12/09/2008 the overall trial start and end dates were changed from 01/11/2007 and 30/04/2010 to 10/04/2008 and 10/10/2010, respectively.

On 15/02/2011 the following changes were made to this trial record:
1. The overall trial end date was changed from 10/10/2010 to 28/02/2012.
2. The target participant number was changed from 320 to 180.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee, 28/12/2008, ref: 07/H0206/62

Primary study design
Interventional

Study design
Open-label two-arm multi-centre phase III randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Advanced gastric cancer

Interventions
Arm A: chemotherapy with docetaxel plus active symptom control for 18 weeks. The participants in this arm will have treatment once every 3 weeks and will receive up to 6 cycles of docetaxel intravenously at a dose of 75 mg/m^2 (total of 18 weeks of treatment).

Arm B: active symptom control for 18 weeks. Active symptom control may include administration of analgesics, anti-emetics, steroids, palliative radiotherapy and/or any other supportive measures deemed appropriate by the treating clinician.

Intervention Type

Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Docetaxel

Primary outcome(s)
Overall survival, measured as the time between the date of randomisation and the date of death from any cause.

Key secondary outcome(s)
1. Time to documented progression
2. Response rates to docetaxel. This will be assessed using the Response Criteria In Solid Tumours (RECIST) at baseline and after 3 and 6 cycles of treatment. The best overall response achieved over the treatment period will be determined
3. Toxicity of docetaxel. Docetaxel related toxicity data will be collected at the end of each of the chemotherapy cycles prior to the start of the next cycle. In addition, all Adverse Events (AEs) will be monitored and recorded from randomisation until 21 days after the last administration of docetaxel
4. Quality of life, assessed using the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire QLQ-C30 vs3 and QLQ-STO22. Quality of life data will be collected at baseline and then after 3, 6, 9, 12, 18 and 24 weeks from start of treatment
5. Health economic evaluation. The EuroQoL (EQ-5D) health outcome instrument is to be used for this assessment. The EQ-5D will be completed at baseline and then at every outpatient visit until death

Completion date
10/10/2010

Eligibility

Key inclusion criteria
1. Patients with histologically confirmed adenocarcinoma of the stomach (including Siewert-Stein type II and III adenocarcinoma of the oesophago-gastric junction)
2. Age 18 years or older
3. Advanced disease not amenable to curative treatment
4. Documented progressive disease while receiving or within 6 months of completion of first line chemotherapy with a platinum and fluoropyrimidine based therapy either for advanced disease or as neoadjuvant/perioperative therapy
5. Estimated life expectancy greater than or equal to 12 weeks
6. Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2
7. Satisfactory haematologic (haemoglobin [Hb] greater than or equal to 10 g/dL, White Blood Cells [WBC] greater than or equal to 3.0 x 10^9/L, Absolute Neutrophil Count (ANC) greater than or equal to 1.5 x 10^9/L, Platelets (Plt) greater than or equal to 100 x10^9/L), renal (creatinine less than or equal to Upper Limit of Normal [ULN]) and hepatic (total Bilirubin less than or equal to ULN, Alanine aminotransferase (ALT) less than or equal to 1.5 x ULN, Alkaline Phosphatase (ALP) less than or equal to 5 x ULN) function
8. Ability to give informed consent
9. Completion of baseline questionnaires (European Organisation for Research and Treatment of

Cancer Quality of Life Questionnaire [EORTC QLQ-C30] and EORTC-QLQ-STO22 [gastric cancer-specific QLQ] and EuroQoL (EQ-5D) questionnaire)
10. Patients of both sexes with reproductive potential must be willing to employ barrier contraceptives whilst on treatment and for 3 months after completion of treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Cerebral or leptomeningeal metastasis
2. Prior chemotherapy with taxanes
3. Peripheral neuropathy
4. More than one prior chemotherapy regimen in advanced setting
5. Previous malignancy except for curatively treated basal cell carcinoma of the skin or cervical intraepithelial neoplasia
6. Pregnant or breastfeeding female patient
7. Any medical or psychiatric condition which would influence the ability to provide informed consent
8. Any other serious or uncontrolled illness which, in the opinion of the investigator, makes it undesirable for the patient to enter the trial

Date of first enrolment
10/04/2008

Date of final enrolment
10/10/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge

United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) (ref: C21276/A7737)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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

Basic results	No	No
Plain English results	No	Yes