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321GO: Three, two or one-drug chemotherapy for advanced gastroesophageal cancer: a feasibility study in frail and/or elderly patients

Submission date
16/03/2008

Recruitment status
No longer recruiting

Registration date
15/07/2008

Overall study status
Completed

Last Edited
31/03/2022

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-setting-up-a-trial-of-chemotherapy-for-frail-and-elderly-patients-with-advanced-cancer-of-the-food-pipe-and-stomach

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MO08/8527

Study information

Scientific Title
321GO: Three, two or one-drug chemotherapy for advanced gastroesophageal cancer: a feasibility study in frail and/or elderly patients

Acronym
321GO

Study objectives
Is it feasible to perform a large randomised controlled trial comparing single-agent, two-drug or three-drug chemotherapy in frail elderly patients with advanced gastroesophageal cancer, for whom standard combination chemotherapy is considered unsuitable.

On 22/02/2011 the overall trial end date was changed from 01/01/2010 to 18/02/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (East) Research Ethics Committee on 01/07/2008

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Incurable gastric or oesophageal carcinoma in frail or elderly patients

Interventions

Starting doses:
Arm 1: EOX (control) - Epirubicin (40 mg/m2), oxaliplatin (104 mg/m2), X capecitabine (500mg /m2 twice a day [bd] for 21 days)
Arm 2: OX - Oxaliplatin (104 mg/m2), X capecitabine (500 mg/m2 bd for 21 days)
Arm 3: X capecitabine (1,000 mg/m2 bd for 14 days)

These doses are 80% of the standard regimens. After 6 weeks (2 cycles), patients will be assessed and considered for escalation to full standard doses, provided no Common Toxicity Criteria (CTC) grade >=2 toxicity has occurred and the patient and clinician agree.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Epirubicin, oxaliplatin, capecitabine

Primary outcome measure
1. The rate of patient randomisation into 321GO over the 18 month recruitment period in the 2 participating cancer networks
2. The number of patients at each participating network considered for palliative chemotherapy for advanced GO cancer, and the proportion randomised into 321GO

Secondary outcome measures
1. The tolerability of each regimen, assessed in terms of the following:
1.1. The incidence of CTCAEv3 grade >= 3 non-haematological toxicities at 6 weeks
1.2. The incidence of SAEs and dose delays/reductions
1.3. The ability/willingness to dose-escalate to 100% at week 6
2. Patient acceptability scores at 12 and 24 weeks
3. Quality of life, nutritional and symptom changes at 0, 12 and 24 weeks:
3.1. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30) with Gastroesophageal module
3.2. 24-point Nottingham Instrumental Activities of Daily Living (IADL) tool
3.3. Mini-nutritional assessment questionnaire
3.4. Mini-Mental State Examination
3.5. Charlson co-morbidity score
3.6. Euroqol (EQ-5D) questionnaire
4. Progression-free survival for the whole group (combining all 3 treatment arms)

Overall study start date
01/09/2008

Completion date
18/02/2011

Eligibility

Key inclusion criteria

1. Both males and females
2. Histologically confirmed carcinoma of the oesophagus, GO-junction or stomach, of either squamous, adenocarcinoma or undifferentiated type
3. With or without distant metastases, but if M0, must be planned for treatment with palliative intent
4. No previous chemotherapy for GO cancer
5. Considered by treating consultant to be fit/suitable for reduced-dose chemotherapy (normally WHO PS <=2)
6. Renal function: Glomerular filtration rate (GFR) (measured or estimated) >=30 ml/min
7. Hepatic function: Aspartate aminotransferase (AST)/ alanine aminotransferase (ALT) <=2.5 x upper limit of normal (ULN) and bili <= 1.5 x ULN
8. Projected life expectancy of at least 3 months
9. Unidimentionally measurable disease on computerised tomography (CT) or magnetic resonance imaging (MRI) scan with the response evaluation criteria in solid tumours (RECIST)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
55

Key exclusion criteria
1. Fit, suitable and willing for standard full-dose combination chemotherapy with EOX (epirubicin, oxaliplatin, X capecitabine) or equivalent
2. Medical or psychiatric condition impairing ability to consent or comply with assessments including Quality of life questionnaire
3. Requiring ongoing treatment with a contraindicated medication
4. Age <18 years

Date of first enrolment
01/09/2008

Date of final enrolment
18/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James' Institute of Oncology
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
The Clinical Trials Research Unit
17 Springfield Mount
Leeds
England
United Kingdom
LS2 9NG

Sponsor type
University/education

Website
http://www.leeds.ac.uk/medicine/nyctru/ctru_contents.htm

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Cancer Research UK (UK)

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Roche UK (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	14/02/2017		Yes	No
Plain English results			31/03/2022	No	Yes