

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/03/2022	Condition category Cancer	<input type="checkbox"/> 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

Contact name

Prof Matt Seymour

Contact details

St James' Institute of Oncology
Bexley Wing
Level 4
St James' University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)113 343 8396
Matt.Seymour@leedsth.nhs.uk

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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. Unidimensionally 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

St James' Institute of Oncology

Leeds

United Kingdom

LS9 7TF

Sponsor information**Organisation**

University of Leeds (UK)

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Industry

Funder Name

Cancer Research UK (UK)

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

Funder Name

Roche UK (UK)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

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