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Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer

Submission date	Recruitment status	[X] Prospectively registered
10/09/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-at-chemotherapy-for-frail-or-elderly-patients-with-advanced-cancer-of-the-stomach-or-food-pipe-go2

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2013-000009-21

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15037

Study information

Scientific Title
GO2 - Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer: a randomised controlled trial

Acronym
GO2

Study objectives
The GO2 study is a randomised controlled trial (RCT) of palliative chemotherapy using oxaliplatin and capecitabine (OxCap) in frail/elderly patients with advanced GO cancer who are not fit to receive standard full-dose chemotherapy, but who are suitable for lower-dose chemotherapy. The trial will compare 3 dose levels of OxCap chemotherapy and a best supportive care (BSC) arm.

The aims of doing this study are:
1. To find out which dose of OxCap achieves the best balance of cancer control,toxicity, patient acceptability and quality of life for frailer patients with advanced cancer of the gullet or stomach.
2. To find out if there are any patient characteristics that could predict better orworse outcomes with chemotherapy at different doses.
3. To find out whether there is any benefit to giving chemotherapy to patients for whom there is substantial uncertainty about the role of chemotherapy.

Eligible and consenting participants will undergo a Comprehensive Health Assessment (CHA). Patients considered likely to benefit from chemotherapy will be randomised to receive one of three dose intensities of OxCap. Patients considered as uncertain to benefit from chemotherapy will be randomised to one of the three dose intensities of OxCap or a BSC arm.

GO2 aims to recruit a minimum of 500 patients across the UK over a 3 year period. It will provide the first RCT evidence to guide the use of palliative chemotherapy in elderly/frail patients with advanced GO cancer, and has the potential to have significant impact upon clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board: Yorkshire and the Humber Leeds East, 02/09/2013, ref: 13/YH/0229

Study design
Randomised interventional treatment 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Upper Gastro-Intestinal Cancer; Disease: Oesophagus

Interventions
GO2 has no fixed sample size. The trial aims to recruit a minimum of 500 participants to the chemotherapy arms, and an additional 30 participants to the BSC arm over 3 years. However, should accrual rates exceed expectations and 750 participants be recruited prior to 3 years. trial closure would then be considered.

Best supportive care (BSC): Participants randomised to receive best supportive care (BSC) will be treated according to local policy.
OxCap 100%: Oxaliplatin 130mg/m^2 day 1 Capecitabine 625mg/m^2 bd x 21 days
OxCap 80%: Oxaliplatin 104mg/m^2 day 1 Capecitabine 500mg^m2 bd x 21 days
OxCap 60%: Oxaliplatin 78mg/m^2 day 1 Capecitabine 375mg/m^2 bd x 21 days

Follow Up Length: 12 months

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Chemotherapy intensity comparison:
1. Progression free survival

Chemotherapy vs best supportive care comparison
1. Overall survival

Secondary outcome measures
Chemotherapy intensity comparison:
1. Participant reported fatigue
2. Time to deterioration of participant reported fatigue
3. Overall treatment utility
4. Quality of life and symptoms
5. Toxicity

6. Overall survival
7. Quality adjusted survival
8. Best response

Chemotherapy vs best supportive care comparison:
1. Participant reported fatigue
2. Quality of life

Comprehensive Health Assessment (CHA) pre-randomisation
EQ-VAS weekly until week 18
Short follow-up questionnaire 3-weekly until week 18, then weeks 27, 36 and 52
Limited Health Assessment week 9

Overall study start date
01/09/2013

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Histologically or cytologically confirmed carcinoma of the oesophagus, GO junction or stomach
2. With or without distant metastases, but if M0, being treated with palliative intent
3. Considered by the treating physician to be fit/suitable for any of the GO2 regimens.
4. Renal function: estimated or measured GFR >=30 ml/min (if in the range 3050ml/min, reduced doses of both drugs must be used)
5. Hepatic function: bilirubin <3 times upper limit of normal (xULN) (if in the range 1.53xULN, reduced doses of both drugs must be used)
6. Bone marrow function: absolute neutrophil count >=1.5 x10^9/l; white blood cell count >=3 x10^9/l; platelets >=100 x10^9/l.
7. Written informed consent
8. Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 780; UK Sample Size: 780

Total final enrolment

558

Key exclusion criteria
1. Fit, suitable (as judged by the treating clinician) and willing for standard full dose combination chemotherapy with EOX or equivalent
2. Previous palliative chemotherapy for GO cancer
3. Medical or psychiatric condition impairing ability to consent or comply with oral chemotherapy or trial assessments (including patient reported outcome measures)
4. Other malignancy if, in the opinion of the treating physician, this would significantly impede interpretation of the outcome of the trial treatment
5. Age <18 years

Date of first enrolment
08/01/2014

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9JT

Study participating centre
58 other sites
United Kingdom
-

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details

Faculty Research Office
University of Leeds
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	quality of life results presented at ESMO	01/10/2019	04/02/2020	No	No
Abstract results	results presented at ASCO	20/05/2019	04/02/2020	No	No
Plain English results			16/10/2020	No	Yes
Results article		01/06/2021	17/05/2021	Yes	No
HRA research summary			28/06/2023	No	No