

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

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

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

Contact name

Mrs Sharon Ruddock

Contact details

Clinical Trials Research Unit (CTRU)
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT

-
s.p.ruddock@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2013-000009-21

Protocol serial number

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 or worse 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

Primary study design

Interventional

Study design

Randomised interventional treatment trial

Study type(s)

Treatment

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/m² day 1 Capecitabine 625mg/m² bd x 21 days

OxCap 80%: Oxaliplatin 104mg/m² day 1 Capecitabine 500mg/m² bd x 21 days

OxCap 60%: Oxaliplatin 78mg/m² day 1 Capecitabine 375mg/m² bd x 21 days

Follow Up Length: 12 months

Study Entry : Single Randomisation only

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Chemotherapy intensity comparison:

1. Progression free survival

Chemotherapy vs best supportive care comparison

1. Overall survival

Key secondary outcome(s)

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

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 30-50 ml/min, reduced doses of both drugs must be used)
5. Hepatic function: bilirubin < 3 times upper limit of normal (xULN) (if in the range 1.5-3xULN, reduced doses of both drugs must be used)
6. Bone marrow function: absolute neutrophil count $\geq 1.5 \times 10^9/l$; white blood cell count $\geq 3 \times 10^9/l$; platelets $\geq 100 \times 10^9/l$.
7. Written informed consent
8. Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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)

ROR

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

Funder(s)

Funder type

Charity

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

Results and Publications

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?
Results article		01/06/2021	17/05/2021	Yes	No
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
HRA research summary			28/06/2023	No	No
Plain English results			16/10/2020	No	Yes