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A second UK Phase III anal cancer trial: a trial of chemoradiation and maintenance therapy for patients with anal cancer

Submission date 31/05/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/05/2001	**Overall study status** Completed	
Last Edited 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00025090

Protocol serial number
ACT II

Study information

Scientific Title
A second UK Phase III anal cancer trial: a trial of chemoradiation and maintenance therapy for patients with anal cancer

Acronym
ACT II

Study objectives
Following completion of ACT I the standard treatment for anal cancer is a combined modality treatment of radiotherapy, 5-Fluorouracil (5-FU) and mitomycin. However, the schedule used in ACT I may not be optimal and an improvement in outcome may be achieved by intensifying.

United Kingdom, European Organisation for Research and Treatment of Cancer (EORTC) and Intergroup pilot studies used three main approaches:
1. Modification of radiotherapy schedule
2. Changing the chemotherapy regimen
3. Additional courses of chemotherapy.

As a result, to avoid using split course radiotherapy a continuous course of radiotherapy (piloted in over 80 patients) will be used in this trial, cisplatin will be compared to mitomycin and patients will be randomised to maintenance chemotherapy.

Cisplatin was chosen as in combination with 5-FU it is active in advanced disease, it produces high Complete Remission (CR) rates in combination with radiotherapy and has activity in other squamous cell carcinomas.

Additional chemotherapy will be given after treatment as neo-adjuvant chemotherapy has not been shown to improve survival when given in combination with radiotherapy in other tumour sites. In addition the toxicity associated with it may impact on the timing of treatment and on the total dose of chemoradiation delivered.

Therefore, the objectives of this trial are as follows:
1. Whether Cisplatin or Mitomycin produces a higher CR rate post treatment
2. Whether Cisplatin or Mitomycin produces a higher grade four acute toxicity
3. Whether maintenance chemotherapy will improve recurrence-free survival

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anal cancer

Interventions
Four treatment arms:
1. 5-Fluorouracil 1000 mg/m^2, days one to four and 29 to 32 by 24 hour continuous infusion and Mitomycin 12 mg/m^2, day one only, intravenous (iv) bolus and no maintenance therapy
2. 5-Fluorouracil 1000 mg/m^2, days one to four and 29 to 32 by 24 hour continuous infusion and Mitomycin 12 mg/m^2, day one only, iv bolus and maintenance therapy (CDDP)
3. 5-Fluorouracil 1000 mg/m^2, days one to four and 29 to 32 by 24 hour continuous infusion and Cisplatin 60 mg/m^2, days one and 29 by iv infusion and no maintenance therapy
4. 5-Fluorouracil 1000 mg/m^2, days one to four and 29 to 32 by 24 hour continuous infusion and Cisplatin 60 mg/m^2, days one and 29 by iv infusion and maintenance therapy (CDDP)

Maintenance therapy consists of:
Two courses 5-FU and Cisplatin, four weeks after the end of primary chemoradiation repeated after three weeks:
5-Fluorouracil 1000 mg/m^2, days one to four and Cisplatin 60 mg/m^2, day one by iv infusion

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
5-Fluorouracil, Mitomycin and Cisplatin

Primary outcome(s)
1. CR rate (at six months):
1.1. 90% to detect an increase from 80% to 90%
1.2. 95% to detect an increase from 85% to 95%
2. Grade four toxicity: 95% to detect a doubling of the 11% Grade four acute toxicity reported in ACT I
3. Recurrence-free survival:
3.1. 80% to detect 11% difference (64% to 75%)
3.2. 99% to detect 16% difference (64% to 80%)

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/08/2007

Eligibility

Key inclusion criteria
1. Histological proof of epidermoid anal carcinoma (includes squamous, basaloid and cloacogenic lesions)
2. Patients fit to receive platinum or mitomycin C based chemotherapy determined by:

2.1. Adequate baseline renal function
2.2. Acceptable haematological parameters
2.3. Liver Function Tests (LFTs) within 2 x normal range
2.4. Adequate cardiac function
2.5. No serious uncontrolled medical conditions (particularly cardiovascular disease)
2.6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex

Key exclusion criteria
1. Anal cancer that has spread to another part of the body
2. Adenocarcinoma or muco-epidermoid anal cancer
3. Lymphoma or melanoma of the anal canal
4. Pre-cancerous cell changes (intraepithelial neoplasia) that have not developed into anal cancer
5. Had your cancer completely removed with an operation
6. Already had treatment for your anal cancer
7. Had radiotherapy to your pelvic area before
8. Had any other cancer in the past
9. Any other serious medical condition

Date of first enrolment
01/02/2001

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
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Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No
Results article	post-hoc analysis results	01/03/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes