

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

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<b>Registration date</b> 31/05/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00025090

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Anal cancer

## Interventions

Four treatment arms:

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

## Intervention Type

Drug

## Phase

Phase II

## Drug/device/biological/vaccine name(s)

5-Fluorouracil, Mitomycin and Cisplatin

## Primary outcome measure

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%)

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/02/2001

**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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

600

**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

England

United Kingdom

## Study participating centre

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

# Sponsor information

## Organisation

Cancer Research UK (CRUK) (UK)

## Sponsor details

PO Box 123

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London

United Kingdom

WC2A 3PX

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kate.law@cancer.org.uk

## Sponsor type

Charity

## Website

<http://www.cancer.org.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, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	01/08/2014		Yes	No
<a href="#">Results article</a>	post-hoc analysis results	01/03/2017		Yes	No