UKCCCR Anal Cancer Trial: Prospective Randomised Trial of Combined Modality Therapy versus Radiation Alone in the Management of Anal Cancer

Submission date	Recruitment status	Prospectively registered
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
21/12/2011	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Not provided at time of registration

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)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Anus cancer

Interventions

- 1. Radiotherapy Alone: Radiotherapy, 45 Gy given in twenty-five fractions over 5 weeks or twenty fractions over 4 weeks.
- 2. Combined Modality Therapy: Radiotherapy as above plus chemotherapy (mitomycin-C and 5-fluorouracil). Chemotherapy to start on the same initial day as radiotherapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cancer drugs

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1990

Completion date

11/03/1994

Eligibility

Key inclusion criteria

- 1. Histological proof of epidermoid carcinoma. This includes lesions referred to as squamous cell, basaloid and cloacogenic carcinoma. Adenocarcinoma, malignant melanoma, mucoepidermoid carcinoma and lymphoma are excluded
- 2. No previous treatment for anal cancer
- 3. No previous radiotherapy to the pelvis
- 4. No history of other malignancy, except adequately treated squamous or basal cell carcinoma of the skin or in situ cervical carcinoma
- 5. No contraindications to either treatment

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Added May 2008: 585

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1990

Date of final enrolment

11/03/1994

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details

MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Sponsor type

Government

ROR

https://ror.org/054225q67

Funder(s)

Funder type

Research organisation

Funder Name

UKCCCR (UK)

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/1996		Yes	No