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

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

UKCCCRANAL1

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 summary

Not 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