East of England Radiotherapy Network:

Anal Cancer Protocol V2.0

Contents

1.0 Indications and patient population

This protocol covers treatment in the following situations:

a. Curative radiotherapy ± concomitant chemotherapy for good prognosis T1N0 tumours; adjuvant radiotherapy (± concomitant chemotherapy) for surgically excised tumours with a margin smaller than 1mm

b. Curative radiotherapy and concomitant chemotherapy for early tumours with standard risk (T1 N0 with poor prognostic factors or T2 N0)

c. Curative radiotherapy and concomitant chemotherapy for locally advanced tumours with high risk (T3/4 Nany or Tany N+ve)

d. Radical radiotherapy with concomitant chemotherapy for patients with anal cancer and borderline performance status

e. Palliative radiotherapy for patients with anal cancer and poor performance status

f. Tumours arising from an area of 5cm around the anal verge will be considered as anal cancer. Tumours arising outside this area will be referred to the skin cancer multidisciplinary team.

1.1 Curative treatment eligibility

1.1a Inclusion criteria

- Localised squamous cell carcinoma of the anus with no evidence of distant metastases (para-aortic nodal involvement could be considered for treatment with radical intent, at the discretion of the treating oncologist)
- Performance status of 0-1 on the ECOG scale, exceptionally 2

1.1b Exclusion criteria

- Inadequate cardiovascular, respiratory, renal, or hepatic function for safe delivery of radiotherapy and concomitant chemotherapy. Patients unfit for concurrent chemoradiotherapy could be considered for radiotherapy alone at the discretion of the treating oncologist.
- Inadequate immobilisation for safe delivery of radiotherapy
- Anal cancer with adenocarcinoma histology type

1.1.c Essential information required for curative patients

- History and clinical examination, performance status, HIV status
- Full blood count, urea and electrolytes, liver function tests
- DPYD testing for Fluropyrimidines

- CT scan of chest, abdomen, and pelvis
- MRI pelvis
- For nodes identified on PET/CT, MDT discussion is recommended to determine which nodes should be included in the high dose volume.
- All female patients should have a per vaginal examination by the treating oncologist or be referred to the gynaecologist for examination.
- Whole body PET/CT in ≥T2 tumours or Tany N+ve
- Biopsy/FNA of any suspicious inguinal nodes
- Trans-anal ultrasound(optional)
- Examination under anaesthesia

1.1.d Optimisation prior to curative radiotherapy treatment

- Patients who are HIV-positive should be discussed with the infectious diseases team and standard CRT considered for those appropriate i.e. low viral load, on HAART, CD4 count >200 cells/mm3 and no other co-morbidities.
- Consider discussing with HIV physicians regarding potential interactions between chemotherapy and anti-retroviral medications.
- Indications for a de-functioning colostomy include tumours infiltrating into the posterior vagina and those with significant faecal incontinence due to sphincter dysfunction (secondary to tumour infiltration).
  It can be considered in those with significant pain or minor incontinence and tumours at risk of mechanical obstruction. The decision to proceed with a de-functioning colostomy is at the discretion of the MDT team with an awareness of the local reversal rate bearing in mind the poor reversal rate observed in ACT II once a stoma has been formed.

2.0 Localisation

Localisation	Notes	
Position	Supine Consider prone if bolus to anus required.	
Bolus	Clinician to decide, based on examination / imaging if tumour is adequately bolused by buttock cheeks. If there is not 5mm of tissue around the whole GTV, suggest using wax bolus sheet / gauze. For excised tumours, mark scar with wire.	
Immobilisation and supports	Supine: Head rest, arms on the chest, knee, and ankle support.	Prone: Use prone pillow, arms above head, knee, and ankle support.
Organ pre-requisites	Bladder	Comfortably full bladder, ideally aim for >250ml

Localisation	Notes	
Contrast	Intravenous contrast, consider oral contrast to delineate small bowel	
	Radio-opaque marker at anal verge or distal point of macroscopic disease	
CT acquisition	Slice thickness:	2-3mm
	Superior scanning limit	Top of L3
	Inferior scanning limit	7cm inferior to anal marker

3.0 Dose prescription & chemotherapy

Intent	Dose (Gy)/#	#/week	Chemotherapy**/ comments
a. Curative for good prognosis, T1 N0 tumours[†]	Gross anal disease (PTVp__5040)= 50.4Gy in 28#	5	Mitomycin 12mg/m2 Day 1 with 5FU 1000mg/m2 days 1-4 and day 29-32 OR Mitomycin 12mg/m2 day 1 with Capecitabine 825mg/m2 BD on days of XRT
b. Curative for early, standard risk (T1/2 N0) tumours*	Elective (PTVe_4000) = 40Gy in28# Gross anal disease (PTVp_5040) = 50.4 Gy in 28#	5	Mitomycin 12mg/m2 Day 1 with 5FU 1000mg/m2 days 1-4 and day 29-32 OR Mitomycin 12mg/m2 day 1 with Capecitabine 825mg/m2 BD on days of XRT
c. Curative for advanced, high risk (T3/4 Nany or Tany N+ve)*	Elective (PTVe_4000) = 40 Gy in 28# Gross nodal disease <3cm (PTVn_5040) = 50.4Gy in 28# Gross nodal disease >3cm (PTVn_5320) = 53.2Gy in 28# Gross anal disease (PTVp_5320) = 53.2 Gy in 28#	5	Mitomycin 12mg/m2 Day 1 with 5FU 1000mg/m2 days 1-4 and day 29-32 OR Mitomycin 12mg/m2 day 1 with Capecitabine 825mg/m2 BD on days of XRT
d. Radical radiotherapy for patients with borderline PS(Toronto Regime)	Phase 1: PTVp + PTVn + PTVe=PTV_3000 = 30Gy in 15# **3-week gap** Phase 2: PTVp + PTVn = PTV_2000/2400=_ 20-24Gy in 10-12#	5 5	Mitomycin 12mg/m2 day 1 with Capecitabine 825mg/m2 BD on days of XRT Capecitabine 825mg/m2 BD on days of XRT
e. Palliative	20Gy in 5 # OR 30Gy in 10#	5 5	No concurrent chemotherapy

[†] For surgically excised tumours with a margin smaller than 1mm, consider adjuvant radiotherapy with or without concurrent chemotherapy
*It is at the clinician's discretion whether to treat T2N0 as early or locally advanced, dependant on prognostic factors such as the grade and site of the tumour or sex and smoking status of the patient.
** Consider applying a dose reduction for concurrent chemotherapy in patients with impaired renal function or elderly patients.

4.0 Target volumes

- Use standard nomenclature as per GHG Consensus Guidelines https://www.thegreenjournal.com/action/showPdf?pii=S0167-8140%2820%2930294-2
- Please refer to the national guidance for VMAT/ IMRT in anal cancer (RCR 2024) for illustrations of contouring
- Fuse the diagnostic MRI (preferably on a flat couch) with the planning CT (optional). The treating consultant should review and approve the registration if used
- The GTV should be determined by the treating clinician using the planning CT, clinical data, MRI, and PET/CT
- The borders of the GTV should not be defined using the PET/CT
- Skin involvement is defined as visible changes to skin such as erythema, ulceration; if skin is normal visually, but on palpation feels thickened and /or oedematous it should be considered as involved

4.1 Curative radiotherapy for good prognosis, T1 N0 tumours

- **GTV_A** = Includes the gross primary anal tumour volume.
- **CTVp_5040** = GTV + 10mm. Following this, manually enlarge to ensure coverage of entire anal canal including outer border, from the anorectal junction (approximately 4cm superiorly from anal verge identified by the radio-opaque marker) to the anal verge including the internal and external anal sphincters. Edit to exclude bone and muscle.
- **PTVp_5040** = CTVp_5040 + 10mm.

4.2 Curative radiotherapy for early, standard risk (T1/2 N0) tumours

- **GTV_A** = Includes the gross primary anal tumour volume.
- **CTVp_5040** = GTV_A + 10mm. Following this, manually enlarge to ensure coverage of entire anal canal including outer border from the ano-rectal junction (approximately 4cm superiorly from anal verge identified by the radio-opaque marker) to the anal verge including the internal and external anal sphincters. Edit to exclude bone and muscle.
- **CTVe_4000** = Elective nodal regions of Internal Iliac, external Iliac, obturator, inguinal, pre-sacral nodes and mesorectum (lower 50mm in patients with no mesorectal nodes).
- **PTVp_5040** = **CTVp_5040** + 10mm.*
- **PTVe_4000** = **CTVe_4000** + 5mm.*

4.3 Curative radiotherapy for locally advanced, high risk (T3/4 Nany or Tany N+ve) tumours or T2N0 at clinician's discretion

- **GTV_A** = Includes the gross primary anal tumour volume.
- **GTV_N** = Includes all involved nodes.

- **CTVp_5320** = GTV_A + 15mm. Following this, manually enlarge to ensure coverage of entire anal canal including outer border from the ano-rectal junction (approximately 4cm superiorly from anal verge identified by the radio-opaque marker) to the anal verge including the internal and external anal sphincters. If no bone or muscle involvement, edit to exclude bone and muscle, if bone or muscle involvement only edit structure free from infiltration.
- **CTVn_5320** = GTV_N + 5mm or **CTVn_5040** if GTV_N <3cm diameter
- **CTVe_4000** = Elective nodal regions of Internal Iliac, external Iliac, obturator, inguinal, pre-sacral nodes and mesorectum (lower 50mm in patients with no mesorectal nodes, whole mesorectum in those with mesorectal nodes present); consider including the ischiorectal fossa, if tumour infiltration more than 5mm into the ischiorectal fossa, clinically or on diagnostic imaging.
- **PTVp_5320** = **CTVp_5320** + 10mm*
- **PTVn_5320** = **CTVn_5320** + 5mm*
- **PTVn_5040 = CTVn_5040** + 5mm*
- **PTVe_4000** = **CTVe_4000** + 5mm*

All PTVs, other than those where skin is involved with tumour, should be edited to lie 5 mm inside the body contour.

*These margins are appropriate for patients treated with daily online imaging. We recommend centres audit their local set-up regularly.

4.4 Palliative radiotherapy

An appropriate regime should be chosen after considering the patients likely prognosis, disease burden, symptoms, and performance status. Palliative re-irradiation can be offered for symptom control e.g., to stop bleeding or pain. Dose and fractionation should be individualised and is beyond the scope of this guideline.

- IMRT/opposed fields to cover all macroscopic disease or symptomatic disease; consider contouring GTV and adding 10-20mm circumferential margins to guide field placement.

5.0 Organs at risk

- Aim for the use of standard nomenclature as per Global Harmonization Group consensus guidelines: https://www.thegreenjournal.com/action/showPdf?pii=S0167-8140%2820%2930294-2

Structure name	Description
Bowel_Small	Contouring should include all individual small bowel loops to at least 20mm above the superior extent of both PTVs. It may be helpful to initially delineate the large bowel ± uterus to exclude these from subsequent delineation of the small bowel.
Genitals	Delineation of the male genitalia should include the penis and scrotum. In women it should include the clitoris, labia majora and minora. An additional avoidance structure avoiding inguinal creases can be utilised at clinician's request.
Bladder	Entire bladder including outer bladder wall.
Femur_Head_L or _R	To be contoured separately on each side. To include the ball of the femur, trochanters, and proximal shaft to the level of the bottom of ischial tuberosities.

5.1 Constraints

Structure name	Constraint	Optimal	Mandatory
PTVp_5320/5040	D99% D95% D50% D5% D2%	>90% >95% Between 99%-101% <105% <107%	>90% >95% Between 97%-101% <107% <110%
PTVe_4000	D99% D95% D50%	>90% >95% <110%	>90% >95% <125%
Bowel_Small	D200cc D150cc D20cc D5cc	<30Gy <35Gy <45Gy <50Gy	<35Gy <40Gy <50Gy <55Gy
FemurHeadNeck_L / _R	D50% D35% D5%	<30Gy <40Gy <50Gy	<45Gy <50Gy <55Gy
Genitals	D50% D35% D5%	<20Gy <30Gy <40Gy	<35Gy <40Gy <55Gy
Bladder	D50% D35% D5%	<35Gy <40Gy <50Gy	<45Gy <50Gy <58GY

6.0 Planning process/ technique

Good prognosis T1N0 tumours

If tumour plus margin is treated, it is at the discretion of the treating oncologist whether inverse plan or 3D conformal plan is used. If IMRT is used, all efforts to reduce dose to OARs to the minimum should be undertaken, as objectives are likely to be easily met.

> For 3D conformal treatment suggest delivery with 6MV photons using gantry angles of 90^0, 180^0 and 270^0.

All other tumours

Inverse plan using simultaneous integrated boost technique delivered with coplanar beams or arc delivery (IMRT, VMAT and Tomotherapy).
A modern dose-calculation algorithm taking tissue inhomogeneity and lateral electron transport into account (type B algorithm) must be used.

For IMRT

Suggested Beam positions if supine: 0°; 310°; 275°; 210°; 150°; 85°; 50°
Suggested Beam positions if prone: 180°; 130°; 95°; 30°; 330°; 265°; 230°

Planning parameters

Prescription Point - 100% to the median dose in the primary PTV (ICRU 83)
Target coverage and OAR requirements, both objectives and mandatory constraints as documented in section 5.1
To make sure hotspots in low dose PTVe_4000 are below 107% (add objective D2% < 107%), an optimisation structure can be created PTVe_4000_opt that is cropped from any boost volumes or the primary PTV.

PTVe_4000_opt	V107% (107% of 40 Gy)	< 2% (Optimal Obj)

Preferred priority of structures in planning:
1) PTV's – these will always take priority over any OAR constraint.
2) Small bowel
3) Femoral Heads
4) Genitalia
5) Bladder

7.0 Peer Review/ Contour QA

- All curative volumes should be prospectively peer-reviewed prior to the start of treatment.
- A description of the contouring (planning note) and of the peer review process including changes made should be saved in the patient record.
- Consider involving a radiologist in the peer review process.
- The peer review process and outcomes should be audited.

8.0 Target verification

Modality	Frequency	Match point	Additional information
kV planar/ MV planar/ CBCT	Daily online imaging. Minimum CBCT performed days1-5 and weekly thereafter as minimum. Online kV/MV images to be performed on other days.	Bone match to PTV	Any deviation from this and 5mm CTV to PTV margins may not be appropriate.

9.0 Side effects

9.1 Acute: Short term side effects during or within a few weeks post radiotherapy (usually temporary)	
Expected (50-100%)	**Initial management (if appropriate)**
Tiredness	Recommend light exercise as tolerated.
Skin soreness, itching, blistering and colour changes	RTOG • Grade 1: Faint or dull erythema; mild tightness and itching of the skin may occur. • Grade 2a: Tender or bright erythema; skin may feel tighter/itchy/sore. • Grade 2b: Patchy moist desquamation; yellow/pale green exudate may be visible on the surface. Soreness and oedema are evident. • Grade 3: Confluent moist desquamation; more pronounced areas of broken skin, yellow/pale green exudate are visible. Soreness and oedema are evident. • Grade 4: Ulceration of the skin; haemorrhage and or necrosis of the skin are evident. Moisturiser: patient to use preferred centre emollient (aloe vera gel, E45 etc.) on intact skin. Hydrogel and non-adhesive/silicon-based dressings on areas of moist desquamation. Steroid creams: topical treatment may be required but should not be used on broken skin or if signs of infection are present. Analgesia: review oral analgesia regime. Consider protosedyl ointment, instillgel before bowel opening. Infection screening: take a swab if there are signs of infection and arrange antibiotic treatment if infection is indicated. Consider for admission or regular wound care review. G4 radiation dermatitis: interrupt treatment until G3.
Hair loss in the treatment area	
Bowel frequency and urgency	

9.1 Acute: Short term side effects during or within a few weeks post radiotherapy (usually temporary)	
Looser stools	Dietary advice: advise to avoid high fibre, high fat foods, spices, caffeine, alcohol, fruit juices and lactulose containing products if appropriate. Recommend adequate oral hydration and consider smaller frequent meals. G2 diarrhoea (increase of 4-6 stools/day): continue with loperamide and oral rehydration, send stool for culture and C.difficile toxins. G3 diarrhoea (increase of 7-9 stools/day): Loperamide, codeine, IV hydration and inpatient management as indicated. Continue radiotherapy but do not treat if localised peritonism; consider suspending chemotherapy if diarrhoea G3 or worse. Consider broad spectrum antibiotics and GCSF if neutropenic (likely Cephalosporin and Metronidazole). If G3 diarrhoea not controlled after above within 48hrs: commence s/c octreotide, titrate according to response. Total Perenteral nutrition should be discussed with the nutrition team. G4 diarrhoea (increase of >10 stools/day): interrupt treatment, admit and provide full supportive treatment until resolved to G2 and reassess daily.
Pain around the anus	
Common (10 – 50%)	**Initial management (if appropriate)**
Mild bowel incontinence	
Urinary frequency	Consider oral NSAIDs if no contraindications for dysuria. Consider antispasmodics for urgency. Consider catheterisation/ convene catheter as appropriate.
Cystitis	Infection screening: check urine dip +/- MSU, consider antibiotics if appropriate.
Nausea and/ or vomiting	G2 vomiting: continue with oral antiemetics. G3 vomiting: SC/IV antiemetics, IV hydration and consider TPN, continue RT. G4 vomiting: interrupt until G 0-2. Analgesia as per WHO pain ladder for proctalgia. Consider cinchocaine with prednisolone suppositories for proctitis.
Sexual organs swollen/ painful	
Less common (Less than 10%)	**Initial management (if appropriate)**

9.1 Acute: Short term side effects during or within a few weeks post radiotherapy (usually temporary)	
Moderate bowel incontinence	
Bleeding from bowel	
Not on current RCR consent form	**Initial management (if appropriate)**
Blood/Bone Marrow Anaemia Neutropenia Thrombocytopaenia Infection	Continue radiotherapy with prophylactic antibiotics (e.g. Ciprofloxacin500mg BD) for G3/4 neutropenia. Continue radiotherapy with transfusion if Hb<8.0g/dL (aiming for Hb of > 10g/dL); interrupt if life threatening consequences. Platelets <50-25^{9}/L, continue radiotherapy and consider platelet transfusion if clinically indicated (e.g., bleeding). Platelets <25^{9}/L, interrupt until >49^{9}/L and consider transfusion.

9.2 Late: Long term side effects – months post radiotherapy (may be permanent)	
Expected (50-100%)	**Initial management (if appropriate)**
Skin thickening or discoloration	Consider referral to laser therapy for problematic radiation induced fibrosis or telangiectasia.
Bowel frequency	Consider Loperamide/Codeine Phosphate for looser stool. Consider referral to specialist surgical units/ local late effect team. Please refer to the Practical management of the Gastrointestinal Symptoms of Pelvic Radiation Disease. Consider investigation of conditions such as: • Bile Acid malabsorption using SeHCAT test. • Small Intestinal Bacterial Overgrowth.
Early menopause	Consider hormone replacement therapy if appropriate.

9.2 Late: Long term side effects – months post radiotherapy (may be permanent)	
Female Infertility	Offer fertility preservation.
Common (10-50%)	**Initial management (if appropriate)**
Mild/ moderate bowel incontinence	
Pain around the anus	Consider steroid suppositories.
Mucus, discharge, and/or wind from back passage	
Bleeding from bowel	
Urinary symptoms	Consider tamsulosin/ anti-muscarinic agents as appropriate.
Vaginal narrowing, shortness, or dryness	Counsel on regular use of vaginal dilators.
Male Infertility	
Change in ejaculate	
Inability to achieve an erection	Consider pharmacological (phosphodiesterase inhibitors) and non-pharmacological interventions for sexual dysfunction.
Less common (Less than 10%)	**Initial management (if appropriate)**
Skin ulceration	

9.2 Late: Long term side effects – months post radiotherapy (may be permanent)	
Severe bowel incontinence	
Constipation	
Anal fissure or anal stenosis	
Urinary incontinence	Pelvic floor exercise. Inco pads for urinary incontinence.
Urinary frequency	
Cystitis	
Perforation or fistula	May require surgery.
Pelvis/ hip bone thinning and/ or fractures	Counsel on bone health including calcium rich diet and vitamin D supplementation.
Lymphoedema	Consider compression bandages, skin care, exercises to use affected muscles to improve lymph drainage and manual lymphatic drainage.
Rare (Less than 1%)	**Initial management (if appropriate)**
A different cancer in the treatment area	
Radiation induced nerve damage in the lower back	

10.0 Follow-up protocol

There is currently no robust evidence on optimal follow up and investigations. Imaging follow-up policies are therefore variable based on existing departmental practices and predicted risk of recurrence in individual patients. The following is a suggested follow-up protocol that could be considered.

10.1 Follow-up protocol for standard-risk patients T1-2 N0

Time from completion of RT	2 weeks	6-8 weeks	12 weeks	Year 1	Year 2	Year 3	Years 4-5
Clinical review	x	including physical exam	x	3 monthly	3-4 monthly	6 monthly	6-12 monthly
MRI *			x	x**		x	
Discharge to GP/ assess for survivor ship clinic							discharge at 5 years

* Consider CT for T2 at clinician's discretion

**MRI at 6 months if no CR, at clinician's discretion

10.2 Follow up protocol for high-risk patients T3-4 or N1[$]

Time from completion of RT	2 weeks	6-8 weeks	12 weeks	6 months	Year 1	Year 2	Year 3	Years 4-5
Clinical review	x	including physical exam	X*	x	3 monthly	3 monthly	3-6monthly	6monthly
MRI			x	x	X**			
CT					x	x	x	
Discharge to GP/ assess for survivor ship clinic								discharge at 5 years

[$]Consider including patients with fistula at presentation, HIV, or unable to have concomitant chemotherapy, in the high-risk group for follow-up.

*Clinical assessment +/- EUA if inadequate response at 12 weeks

**consider if residual disease

11.0 Reference

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12.0 Members of the protocol drafting committee

- Cambridge University Hospital NHS Foundation Trust: Rashmi Jadon, Daniel Welford, Jennifer Mehrer
- East Suffolk and North Essex NHS Foundation Trust (Colchester): Sadaf Usman, Clair McKeown, Sandra Huff
- East Suffolk and North Essex NHS Foundation Trust (Ipswich): Bruce Sizer, Sue Downes, Lindsey Sorroll
- Mid and South Essex NHS Foundation Trust: M. Rafiqul Islam (Chair), Jeffrey Rubashingham, Joe Hobson, Nicky Whilde
- Norfolk and Norwich University Hospital NHS Foundation Trust: Andrew Ho, Christopher Beck, Anthi Alexandrou, Ghafour Hallaji Zahmatkesh
- North West Anglia NHS Foundation Trust: Catherine Jephcott, Aileen Considine, Emma Orchard, Karen Lemoine

13.0 Amendment History

A record of changes in this document:

Date	Updated version number	Previous version number	Page Number/Section (updated version)	Details
06.02.23	V1.0			New Document
29.07.24	V2.0	V1.0	Section 4	Target volume information updated
			Section 5.1	Constraint information updated
			Section 6	Planning parameter information updated
			Section 10	Side effect information updated in line with RCR anal cancer consent form
			Section 11	References updated