

# PLATO - Personalising anal cancer radiotherapy d

<b>Submission date</b> 13/07/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/08/2016	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

1. <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-lower-dose-of-chemoradiotherapy-or-observation-for-early-stage-anal-cancer>
2. <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-higher-doses-of-chemoradiotherapy-for-people-with-locally-advanced-anal-cancer>
3. <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-lower-dose-of-chemoradiotherapy-for-people-with-anal-cancer-that-hasnt-spread>

## Contact information

### Type(s)

Public

### Contact name

Mrs Sharon Ruddock

### Contact details

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Leeds Institute of Clinical Trials Research  
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Leeds  
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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

204585

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 31184, IRAS 204585

## Study information

**Scientific Title**

PLATO - Personalising Anal cancer radioTherapy dose - Incorporating Anal Cancer Trials (ACT) ACT3, ACT4 and ACT5

**Acronym**

PLATO

**Study objectives**

PLATO is an integrated protocol, comprising 3 separate trials (ACT3, ACT4 and ACT5) which aims to optimise radiotherapy dose (in combination with chemotherapy) for low-, intermediate- and high-risk anal cancer.

**ACT3:**

ACT3 is a non-randomised phase II trial for patients with early, small tumours who have undergone surgery (local excision). The aim of this study is to determine whether a treatment strategy of surgery alone, i.e. no further treatment, for patients with margins >1mm, and highly selective low-dose radiotherapy with chemotherapy for patients with close margins  $\leq 1$ mm, results in acceptably low rates of cancer recurrence.

**ACT4:**

ACT4 is a randomised phase II trial for patients with intermediate-risk disease. The aim of this study is to compare standard-dose chemoradiotherapy (50.4Gy in 28 fractions) with reduced-dose chemoradiotherapy (41.4Gy in 23 fractions), to see if less radiotherapy is able to maintain the excellent success rates in treating the cancer, while reducing the side effects of treatment.

**ACT5:**

ACT5 is a randomised seamless pilot/phase II/phase III trial for patients with locally advanced anal cancer. The aim of this study is to compare standard-dose chemoradiotherapy (53.2Gy in 28 fractions) with two higher doses of chemoradiotherapy (58.8Gy and 61.6Gy, both in 28 fractions), to see if giving a higher dose of radiotherapy reduces the chance of the cancer coming back, whilst not causing too many extra side effects.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 06/07/2016, ref: 16/YH/0157

**Study design**

Both; Interventional; Design type: Treatment, Drug, Radiotherapy, Active Monitoring

**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 the contact details to request a patient information sheet

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

Anal cancer

## Interventions

Current interventions as of 03/04/2023:

ACT3 (recruitment end date: 31/10/2023):

Observation arm

No further treatment after local excision.

Intervention arm

Either a 3D conformal plan or a single phase inverse-planned IMRT treatment plan delivered with multiple fields, or arc techniques. Choice of delivery technique is at the discretion of the treating clinician.

PTV\_A = 41.4Gy in 23F (1.8Gy per F) in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT4 (recruitment end date: 01/12/2020):

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV\_E) and to the areas of gross tumour (PTV\_A). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

Standard-dose arm

PTV\_A: 50.4Gy in 28F in 5.5 weeks

PTV\_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy: Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 28 days

Reduced-dose (experimental) arm

PTV\_A: 41.4Gy in 23F in 4.5 weeks

PTV\_E: 34.5Gy in 23F in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT5 (recruitment end date: 31/08/2023):

All patients will receive IMRT where different dose fractionations are delivered to the elective

nodal region (PTV\_E) and to the areas of gross tumour (PTV\_A and PTV\_N). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

#### Standard-dose arm

PTV\_A: 53.2Gy in 28F in 5.5 weeks

PTV\_N: 50.4Gy in 28F in 5.5 weeks (involved nodes  $\leq 3\text{cm}$ )

53.2Gy in 28F in 5.5 weeks (involved nodes  $>3\text{cm}$ )

PTV\_E: 40.0Gy in 28F in 5.5 weeks

#### Dose escalation arm 1

PTV\_A: 53.2Gy in 28F in 5.5 weeks

PTV\_Boost: 58.8Gy in 28F in 5.5 weeks

PTV\_N: 53.2Gy in 28F in 5.5 weeks (involved nodes  $\leq 3\text{cm}$ )

53.2Gy in 28F in 5.5 weeks (involved nodes  $>3\text{cm}$ )

PTV\_E: 40.0Gy in 28F in 5.5 weeks

#### Dose escalation arm 2

PTV\_A: 53.2Gy in 28F in 5.5 weeks

PTV\_Boost: 61.6Gy in 28F in 5.5 weeks

PTV\_N: 53.2Gy in 28F in 5.5 weeks (involved nodes  $\leq 3\text{cm}$ )

53.2Gy in 28F in 5.5 weeks (involved nodes  $>3\text{cm}$ )

PTV\_E: 40.0Gy in 28F in 5.5 weeks

#### Chemotherapy in all ACT5 arms (centre choice):

Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 28 days,

or

Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & 5-FU 1000mg/m<sup>2</sup> per 24 hours by continuous iv infusion Days 1-4 and Days 29-32

#### Follow-up (ACT3, ACT4 and ACT5)

All patients will be followed up at the following time points:

1. 6 weeks
2. 3-monthly (Years 1-2)
3. 6 monthly (Year 3), then
4. Annually Annually (Years 4+ until 3 years after the last participant has completed treatment or death)+

All timings are from the end of treatment, except the ACT3 observation arm, which is from the date of registration.

#### Registration / Randomisation process

Following confirmation of written informed consent and eligibility, participants will be registered (ACT3) or randomised (ACT4/5) into the trial by an authorised member of staff at the trial site. Registration/randomisation will be performed centrally using the CTRU automated 24-hour system which can be accessed via the web or telephone.

#### ACT4:

Patients will be randomised on a 1:2 basis (standard-dose:reduced-dose) to receive either standard-dose IMRT in combination with chemotherapy or reduced-dose IMRT in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following

participant characteristics:

1. T-stage (T1, T2)
2. N-stage (N0, NX)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Randomising centre

ACT5:

For the pilot study and Phase II trial, patients will be randomised on a 1:1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or one of two increased-dose experimental arms of IMRT with SIB in combination with chemotherapy. In the Phase III trial, participants will be randomised on a 1:1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or an increased dose arm of IMRT with SIB in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T2/3, T4)
2. N-stage (NX/0/1, N2/3)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Chemotherapy regimen (5FU, Capecitabine)
6. Randomising centre

Previous interventions:

ACT3:

Observation arm

No further treatment after local excision.

Intervention arm

Either a 3D conformal plan or a single phase inverse-planned IMRT treatment plan delivered with multiple fields, or arc techniques. Choice of delivery technique is at the discretion of the treating clinician.

PTV\_A = 41.4Gy in 23F (1.8Gy per F) in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 23 days

ACT4:

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV\_E) and to the areas of gross tumour (PTV\_A). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

Standard-dose arm

PTV\_A: 50.4Gy in 28F in 5.5 weeks

PTV\_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy: Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 28 days

Reduced-dose (experimental) arm

PTV\_A: 41.4Gy in 23F in 4.5 weeks

PTV\_E: 34.5Gy in 23F in 4.5 weeks

Chemotherapy: Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 23 days

#### ACT5:

All patients will receive IMRT where different dose fractionations are delivered to the elective nodal region (PTV\_E) and to the areas of gross tumour (PTV\_A and PTV\_N). A single phase inverse-planned IMRT treatment plan should be produced and delivered with multiple fields or arc techniques.

#### Standard-dose arm

PTV\_A: 53.2Gy in 28F in 5.5 weeks

PTV\_N: 50.4Gy in 28F in 5.5 weeks (involved nodes  $\leq 3$ cm)

53.2Gy in 28F in 5.5 weeks (involved nodes  $> 3$ cm)

PTV\_E: 40.0Gy in 28F in 5.5 weeks

#### Dose escalation arm 1

PTV\_A: 53.2Gy in 28F in 5.5 weeks

PTV\_Boost: 58.8Gy in 28F in 5.5 weeks

PTV\_N: 53.2Gy in 28F in 5.5 weeks (involved nodes  $\leq 3$ cm)

53.2Gy in 28F in 5.5 weeks (involved nodes  $> 3$ cm)

PTV\_E: 40.0Gy in 28F in 5.5 weeks

#### Dose escalation arm 2

PTV\_A: 53.2Gy in 28F in 5.5 weeks

PTV\_Boost: 61.6Gy in 28F in 5.5 weeks

PTV\_N: 53.2Gy in 28F in 5.5 weeks (involved nodes  $\leq 3$ cm)

53.2Gy in 28F in 5.5 weeks (involved nodes  $> 3$ cm)

PTV\_E: 40.0Gy in 28F in 5.5 weeks

#### Chemotherapy in all ACT5 arms (centre choice):

Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & Capecitabine 852mg/m<sup>2</sup> oral bd 5 days/week (on days of radiotherapy) for 28 days,

or

Mitomycin C 12mg/m<sup>2</sup> iv Day 1 & 5-FU 1000mg/m<sup>2</sup> per 24 hours by continuous iv infusion Days 1-4 and Days 29-32

#### Follow-up (ACT3, ACT4 and ACT5)

All patients will be followed up at the following time points:

1. 6 weeks
2. 3-monthly (Years 1-2)
3. 6 monthly (Year 3), then
4. Annually (Years 4+ until 3 years post close of recruitment or death)

All timings are from the end of treatment, except the ACT3 observation arm, which is from the date of registration.

#### Registration / Randomisation process

Following confirmation of written informed consent and eligibility, participants will be registered (ACT3) or randomised (ACT4/5) into the trial by an authorised member of staff at the trial site. Registration/randomisation will be performed centrally using the CTRU automated 24-hour system which can be accessed via the web or telephone.

#### ACT4:

Patients will be randomised on a 1:2 basis (standard-dose:reduced-dose) to receive either standard-dose IMRT in combination with chemotherapy or reduced-dose IMRT in combination

with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T1, T2)
2. N-stage (N0, NX)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Randomising centre

#### **ACT5:**

For the pilot study and Phase II trial, patients will be randomised on a 1:1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or one of two increased-dose experimental arms of IMRT with SIB in combination with chemotherapy. In the Phase III trial, participants will be randomised on a 1:1 basis to receive either standard-dose IMRT in combination with chemotherapy, or the most 'acceptable' increased dose arm of IMRT with SIB in combination with chemotherapy. A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following participant characteristics:

1. T-stage (T2/3, T4)
2. N-stage (NX/0/1, N2/3)
3. Gender (M, F)
4. HIV status (positive, negative)
5. Chemotherapy regimen (5FU, Capecitabine)
6. Randomising centre

#### **Intervention Type**

Other

#### **Primary outcome measure**

Locoregional failure (failure at the primary site (local) and/or surrounding nodal sites (regional) i. e. any failure within the pelvis up to the level of the sacral promontory) at 3 years post close of recruitment.

#### **Secondary outcome measures**

1. Acute toxicities, assessed according to the current NCI-CTCAE or RTOG (for skin toxicity) criteria, during each week of treatment (with the exception of the ACT3 observation arm)
2. Late toxicities, measured by patient reported outcomes via EORTC QLQ-C30 and CR29 questionnaires at 6 weeks, 6, 12, 24 and 36 months post the end of treatment
3. Treatment compliance, measured on a weekly basis by assessment of total dose of radiotherapy received, duration of treatment, delays to treatment due to toxicity, and any chemotherapy dose modifications
4. Clinical response rate (cRR) (ACT4 and 5), assessed by MRI imaging in accordance with the Tumour Regression Grading System at 3 and 6 months post end of treatment
5. Disease-free survival (DFS), defined as time from randomisation to first documented evidence of pelvic failure.
6. Colostomy-free survival (CFS), measured at baseline, prior to the start of treatment and throughout follow-up and will look at patients who have a pre-treatment colostomy that is still present at 12 months post end of treatment, patients who have a colostomy fitted due to a treatment related toxicity or local disease failure
7. Progression-free survival (PFS), defined as time from randomisation to first documented evidence of disease progression or death from any cause

8. Overall survival (OS), defined as time from randomisation to date of death from any cause  
9. Patient Reported Outcome Measures (PROMs), assessed by EORTC QLQ-C30 and CR29 questionnaires at baseline, end of treatment and 6 weeks, 6, 12, 24 and 36 months post the end of treatment

Descriptive outcomes:

1. Pattern of pelvic failures i.e. site and position of failure
2. Proportion of participants undergoing salvage surgery (ACT4 and 5)

**Overall study start date**

01/06/2015

**Completion date**

28/02/2027

## Eligibility

### Key inclusion criteria

Key inclusion criteria for all three trials include:

1. Provision of written informed consent
2. Histologically-proven, invasive primary squamous, basaloid, or cloacogenic carcinoma of the anus
3. Adequate bone marrow, hepatic and renal function
4. HIV negative or HIV positive and receiving effective antiretroviral therapy and CD4 count >200
5. Aged 16 years or over
6. Fit for all protocol defined treatments
7. Prepared to practice methods of contraception during treatment and until 6 months post end of treatment
8. Able to undergo all mandated staging and follow-up investigations, including MRI

Trial-specific inclusion criteria:

ACT3

T1 N0 or Nx anal margin tumour treated by local excision; ECOG performance status 0-2

ACT4

T1-2 up to 4cm N0 or Nx anal canal or anal margin tumour; ECOG performance status 0-1

ACT5

T2 N1-3 or T3-4 Nany anal canal or anal margin tumour; ECOG performance status 0-1

### Participant type(s)

Patient

### Age group

Adult

### Lower age limit

16 Years

### Sex

Both



**Target number of participants**

Planned sample size = 711; UK sample size = 701. ACT3: 90 Over 3 Years; ACT4: 162 Over 2 Years and ACT5: 459 Over 5 Years

**Total final enrolment**

709

**Key exclusion criteria**

Key exclusion criteria for all three trials include:

1. Definite evidence of metastatic disease
2. Prior invasive malignancy unless disease-free for a minimum of 3 years (excluding basal cell carcinoma of the skin or other in situ carcinomas)
3. Prior systemic chemotherapy for anal cancer
4. Prior radiotherapy to the pelvis
5. Uncontrolled cardiorespiratory comorbidity
6. Pregnant or lactating
7. Immunocompromised (organ transplant)

Trial-specific exclusion criteria:

ACT3

Where a piecemeal local excision precludes assessment of tumour size and margin status

**Date of first enrolment**

01/09/2016

**Date of final enrolment**

31/08/2023

**Locations****Countries of recruitment**

England

Ireland

Northern Ireland

Scotland

United Kingdom

Wales

**Study participating centre**

St James's University Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)

Beckett Street

Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**

**Oxford Cancer and Haematology Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Churchill Hospital  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 7LE

**Study participating centre**

**Mount Vernon Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Rickmansworth Road  
Northwood  
United Kingdom  
HA6 2RN

**Study participating centre**

**Velindre Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Velindre Road  
Whitchurch  
Cardiff  
United Kingdom  
CF14 2TL

**Study participating centre**

**Bristol Haematology and Oncology Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Horfield Road  
Bristol  
United Kingdom  
BS2 8ED

**Study participating centre**

**Sussex Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Royal Sussex County Hospital  
Brighton  
United Kingdom  
BN2 5BE

**Study participating centre**

**Guy's Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre**

**Royal Surrey County Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Egerton Road

Guildford

United Kingdom

GU2 7XX

**Study participating centre**

**The Royal Marsden Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Fulham Road

London

United Kingdom

SW3 6JJ

**Study participating centre**

**The Royal Marsden Hospital (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Downs Road

Sutton

United Kingdom

SM2 5PT

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust (ACT3, ACT4 or ACT5 from pilot phase onwards)**

Addenbrooke's Hospital

Hills Road

Cambridge

United Kingdom

CB2 0QQ

**Study participating centre**

**Beatson West of Scotland Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN

**Study participating centre**  
**Edinburgh Cancer Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**  
Western General Hospital  
Crewe Road  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**  
**North Wales Cancer Treatment Centre (ACT3, ACT4 or ACT5 from pilot phase onwards)**  
Glan Clwyd Hospital  
Rhyl  
United Kingdom  
LL18 5UJ

**Study participating centre**  
**Aberdeen Royal Infirmary**  
Foresterhill  
Aberdeen  
United Kingdom  
AB25 2ZN

**Study participating centre**  
**Castle Hill Hospital**  
Castle Road  
Cottingham  
United Kingdom  
HU16 5JQ

**Study participating centre**  
**Charing Cross Hospital**  
Fulham Palace Road  
London  
United Kingdom  
W6 8RF

**Study participating centre**  
**Cheltenham General Hospital**  
Sandford Road  
Cheltenham  
United Kingdom  
GL53 7AN

**Study participating centre**  
**City Hospital**  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**  
**Clatterbridge Cancer Centre**  
Clatterbridge Road  
Bebington  
Wirral  
United Kingdom  
CH63 4JY

**Study participating centre**  
**Colchester General Hospital**  
Turner Road  
Colchester  
United Kingdom  
CO4 5JL

**Study participating centre**  
**Maidstone Hospital**  
Hermitage Lane  
Maidstone  
United Kingdom  
ME16 9QQ

**Study participating centre**

**Northampton General Hospital**  
Cliftonville  
Northampton  
United Kingdom  
NN1 5BD

**Study participating centre**  
**Queen Elizabeth Hospital**  
Mindelsohn Way  
Edgbaston  
Birmingham  
United Kingdom  
B15 2GW

**Study participating centre**  
**Royal Berkshire Hospital**  
London Road  
Reading  
United Kingdom  
RG1 5AN

**Study participating centre**  
**Royal Devon and Exeter Hospital**  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**  
**Royal Free Hospital**  
Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre**  
**Royal Preston Hospital**  
Sharoe Green Lane  
Fulwood

Preston  
United Kingdom  
PR2 9HT

**Study participating centre**

**Singleton Hospital**

Sketty Lane  
Sketty  
Swansea  
United Kingdom  
SA2 8QA

**Study participating centre**

**Southampton General Hospital**

Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**

**St Bartholomew's Hospital**

West Smithfield  
London  
United Kingdom  
EC1A 7BE

**Study participating centre**

**The Christie Hospital**

Wilmslow Road  
Manchester  
United Kingdom  
M20 4BX

**Study participating centre**

**The James Cook University Hospital**

Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**University College Hospital**  
235 Euston Road  
London  
United Kingdom  
NW1 2BU

**Study participating centre**  
**Weston Park Hospital**  
Whitham Road  
Sheffield  
United Kingdom  
S10 2SJ

## **Sponsor information**

**Organisation**  
University of Leeds

**Sponsor details**  
Medicine and Health Faculty Office  
Worsley Building  
Leeds  
England  
United Kingdom  
LS2 9JT

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/024mrxd33>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Cancer Research 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**

To maintain the scientific integrity of the trial, data will not be released prior to the first publication of the analysis of the primary endpoint, either for trial publication or oral presentation purposes, without the permission of the DMEC and TSC. In addition, individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the trial until the first publication of the analysis of the primary endpoint. An electronic copy of peer-reviewed, published papers arising from this research will be deposited in the Europe PubMed Central database.

**Intention to publish date**

28/02/2028

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

The datasets generated during the current study will be available on request from the Clinical Trials Research Unit at the University of Leeds.

De-identified individual participant data datasets generated during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generate datasets to be involved in subsequent uses of those datasets.

Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	investigation of prognostic factors	20/05/2021	25/05/2021	Yes	No
<a href="#">Abstract results</a>		01/10/2019	14/11/2022	No	No
<a href="#">Poster results</a>			14/11/2022	No	No
<a href="#">Plain English results</a>	ACT4 early results summary version 1.0	05/06/2023	05/06/2023	No	Yes
<a href="#">Plain English results</a>	ACT5 early results summary version 1.0	23/06/2023	26/06/2023	No	Yes
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>	ACT4		24/08/2023	No	Yes
<a href="#">Protocol file</a>	version 8.0	07/02/2024	10/10/2024	No	No
<a href="#">Protocol file</a>	version 9.0	04/12/2024	24/01/2025	No	No
<a href="#">Interim results article</a>		02/05/2025	08/05/2025	Yes	No