ISRCTN88455282 https://doi.org/10.1186/ISRCTN88455282

PLATO - Personalising anal cancer radiotherapy d

Submission date 13/07/2016	**Recruitment status** No longer recruiting	✓ Prospectively registered ? Protocol not yet added ? SAP not yet added ✓ Results added ? Raw data not yet added ✓ Record updated in last year
Registration date 03/08/2016	**Overall study status** Ongoing	
Last Edited 11/09/2023	**Condition category** Cancer	

Plain English Summary
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
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 0113 343 7903
plato@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
204585

ClinicalTrials.gov number

Protocol/serial number
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 hypothesis
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 ≤1mm, 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 below to request a patient information sheet

Condition
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/m2 iv Day 1 & Capecitabine 852mg/m2 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/m2 iv Day 1 & Capecitabine 852mg/m2 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/m2 iv Day 1 & Capecitabine 852mg/m2 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: 53.2.Gy in 28F in 5.5 weeks
PTV_N: 50.4Gy in 28F in 5.5 weeks (involved nodes ≤3cm)
53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)
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 ≤3cm)
53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)
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 ≤3cm)
53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)
PTV_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy in all ACT5 arms (centre choice):
Mitomycin C 12mg/m2 iv Day 1 & Capecitabine 852mg/m2 oral bd 5 days/week (on days of radiotherapy) for 28 days,
or
Mitomycin C 12mg/m2 iv Day 1 & 5-FU 1000mg/m2 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/m2 iv Day 1 & Capecitabine 852mg/m2 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/m2 iv Day 1 & Capecitabine 852mg/m2 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/m2 iv Day 1 & Capecitabine 852mg/m2 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: 53.2.Gy in 28F in 5.5 weeks
PTV_N: 50.4Gy in 28F in 5.5 weeks (involved nodes ≤3cm)
53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)
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 ≤3cm)
53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)
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 ≤3cm)
53.2Gy in 28F in 5.5 weeks (involved nodes >3cm)
PTV_E: 40.0Gy in 28F in 5.5 weeks

Chemotherapy in all ACT5 arms (centre choice):
Mitomycin C 12mg/m2 iv Day 1 & Capecitabine 852mg/m2 oral bd 5 days/week (on days of radiotherapy) for 28 days,
or
Mitomycin C 12mg/m2 iv Day 1 & 5-FU 1000mg/m2 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

Overall study end date
28/02/2027

Eligibility

Participant 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

Participant 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 (exluding 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

Recruitment start date
01/09/2016

Recruitment end date
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
Saint Luke's Centre for Radiation Oncology at Beaumont Hospital (ACT5 from phase III onwards)
Beaumont Road
Dublin
Ireland
9

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)
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?
Other publications	investigation of prognostic factors	20/05/2021	25/05/2021	Yes	No
Abstract results		01/10/2019	14/11/2022	No	No
Poster results			14/11/2022	No	No
Plain English results	ACT4 early results summary version 1.0	05/06/2023	05/06/2023	No	Yes
Plain English results	ACT5 early results summary version 1.0	23/06/2023	26/06/2023	No	Yes
HRA research summary	ACT4		28/06/2023	No	No
Plain English results			24/08/2023	No	Yes