ISRCTN73441175 https://doi.org/10.1186/ISRCTN73441175

HIV-Anal Cancer: Person-centred care

Submission date
17/09/2024

Recruitment status
No longer recruiting

Registration date
03/10/2024

Overall study status
Completed

Last Edited
10/03/2026

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People living with HIV and anal cancer should get the care that meets all their needs. This does not always happen when services only focus on one health issue.
This new study will work with people living with HIV who are also being treated for anal cancer. This is to find out what matters most and how to improve cancer services.
We already know that people who get the care they need do better. They are more likely to take treatments and look after themselves. They are less likely to need extra hospital services.
People living with HIV are getting older and are more likely to get other illnesses that need treatment. They face stigma in society.
Although anal cancer is rare, HIV increases the risk and it occurs earlier. The incidence of anal cancer in the general population is 1.6 per 100,000 person-years. Among men who have sex with men and who are living with HIV, this is about 89 per 100,000 person-years.
Treatment is very effective but can also cause side effects that affect long-term quality of life. These affect the skin, bowel, bladder and sexual function. Cancer services do not always know how bad this impact is for people. This can mean that people suffer, often on their own, where better options could be available.
The researchers want to work in equal partnership with people living with HIV who have direct experience of treatment for anal cancer. This way of working is called co-production. The study aims to use co -production to design new models of care and support materials to make sure this group of patients gets the care that meets all their needs.

Who can participate?
Lived experience participants: People living with HIV, 18 years and above, who have had a diagnosis of anal cancer in the last 5 years. We would also like to hear from those who closely support them such as family members, partners or friends.
Stakeholder participants: Healthcare professionals with perspectives representative of different stages in the patient pathway. Representatives of relevant charities and advocacy groups that provide support for this group of patients

What does the study involve?
Interviews:
Lived experience participants will first be approached by their clinical team and referred to the research team who will take consent to conduct an interview. The interview will include questions about anal cancer treatment and its impact, coping strategies and support needs and

what could be improved. Stakeholder participants will also take part in interviews in which they will be asked to share their perspectives on assessing needs and providing information and care for this group, identifying any areas that they believe require improvement.
Intervention Development Group Meetings:
The working group with both patient participants and healthcare staff/other stakeholders will meet three times and will work together to develop new models of care and support materials. During the meetings, findings from the interviews will be presented and ideas for improvement sought from all members. Participants will discuss everyone's ideas and work together to develop them until the final content for improved care during treatment is agreed. As the co-production progresses in these meetings new ways of working and resources, for example, patient information will be developed.

What are the possible benefits and risks of participating?
The study is not designed to provide participants with direct benefits. However, it may be rewarding for participants to work with others who have had similar experiences and be part of a project to design better care.
It is possible that the interviews may bring back bad memories for participants. There will be an option to stop at any time and participants will be signposted to information about support available within their hospital from the clinical team.

Where is the study run from?
The sponsor of this study is The Royal Marsden NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
April 2024 to March 2026

Who is funding the study?
This study is financially supported by National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Emma Hainsworth, Emma.hainsworth@rmh.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Susanne Cruickshank

ORCID ID
https://orcid.org/0000-0003-0204-4739

Contact details
Applied Health Research Group
Royal Marsden Hospital, Fulham Road
London
United Kingdom
SW3 6JJ
+44 (0)20 7811 8516
susanne.cruickshank@rmh.nhs.uk

Type(s)
Public, Scientific

Contact name
Dr Emma Hainsworth

ORCID ID
https://orcid.org/0000-0003-3171-4201

Contact details
Applied Health Research Group
Royal Marsden Hospital, Fulham Road
London
United Kingdom
SW3 6JJ
+44 (0)20 7811 8516
emma.hainsworth@rmh.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
333504

Central Portfolio Management System (CPMS)
58211

Protocol serial number
CCR 6037

Study information

Scientific Title
Living with HIV and treated for Anal Cancer: an exploratory study using a co-production approach to deliver person-centred care

Acronym
HIV-AC: Person-centred care

Study objectives
Aim: To co-produce a feasible and acceptable complex intervention for improving experiences of care and health related quality of life for people living with HIV who receive pelvic chemoradiotherapy for anal cancer

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 03/09/2024, West of Scotland Research Ethics Service (Ward 11, Dykebar Hospital Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/0114

Primary study design
Other

Study design
Qualitative exploratory methods following a three stage multi-method framework for the co-production and prototyping of interventions. Single centre with two PIC sites

Study type(s)
Other

Health condition(s) or problem(s) studied
People living with HIV and treated for anal cancer

Interventions
Observational study
This study uses a co-production methodology in which a person-centred intervention will be developed by researchers alongside stakeholders to align research and service development and increase research impact. Co-production involves the equitable engagement of partners all the way through the research process emphasising power sharing, reciprocity and mutual learning. A three stage multi-method framework for co-producing and prototyping interventions has been developed.
Stage 1: Data will be collected by evidence review, observation and in-depth interviews with lived experience participants (n=20) and stakeholders (n=15) involved in their care and support. Deliverable Stage 1: A rich and detailed description of the experiences of people living with HIV undergoing treatment for anal cancer - drawn from patient participant accounts, interviews with relevant stakeholders and focused observation of the clinical setting. A long list of priority needs during and after treatment will also be produced. The outcomes from all methods will feed into stage 2, the co-production of the intervention.

Stage 2: Three Intervention Development Meetings will be held made up of patients and stakeholders. The findings of Stage 1 will be discussed and appropriate intervention content will be co-produced along with associated resources using an action research cycle. Deliverable Stage 2: A draft intervention and associated resources will be produced

Stage 3: During the final prototype phase, two separate meetings of clinical staff (n= 10) and patient participants (n=5) will provide final feedback and comments before the final prototype is developed. Deliverable Stage 3: A pilot intervention and associated resources will be produced.

Intervention Type
Other

Primary outcome(s)
The development of a pilot person-centred intervention, associated resources and guidance on delivery methods using interviews and focus group discussions with patients and stakeholders, guided by a co-production approach

Key secondary outcome(s)
A rich and detailed description of the experiences of people living with HIV and undergoing treatment for anal cancer drawn from patient and stakeholder interviews

Completion date
01/03/2026

Eligibility

Key inclusion criteria
Lived Experience participants:
1. HIV positive
2. Anal cancer diagnosis within the last 5 years
3. 18 years and upwards
4. Has received pelvic chemoradiotherapy for anal cancer

Stakeholder participants
1. Healthcare professionals of all disciplines involved in the care and support of people living with HIV who are being treated for anal cancer
2. Members of charitable organisations and advocacy groups with relevant knowledge

Participant type(s)
Carer, Health professional, Patient, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Lived experience participants:
1. Has received surgery alone or laser ablation for early-stage anal cancer/anal intraepithelial neoplasia

Date of first enrolment
04/10/2024

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Marsden Hospital
Fulham Road
London
England
SW3 6JJ

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available