ISRCTN17304563 https://doi.org/10.1186/ISRCTN17304563

TROPICCANA: A new blood test to monitor treatment in patients with cervical cancer

Submission date 05/02/2026	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 17/04/2026	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 17/04/2026	**Condition category** Cancer	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Every year in the UK approximately 3000 patients are diagnosed with cervix cancer caused by Human Papilloma Virus (HPV) infection. The standard treatment for cervix cancer that cannot be removed with surgery is either radiotherapy alone or chemoradiotherapy and brachytherapy. At 12 weeks after treatment has completed all patients will have an MRI and a PET/CT scan. Mostly, these scans will show a good result, but sometimes it can be difficult to say that the cancer has completely gone. This can cause concern to patients and lead to other tests and biopsies and sometimes surgery. However, most often, if the scans are repeated 3 months later, the cancer will have resolved. Cervix cancer can sometimes relapse after successful treatment and early detection of relapse is vital to the success of subsequent treatment. Currently we rely on clinical inspection of the cervix and annual scans to follow up and detect relapse. Therefore, a more reliable test to both response at 3 months and to monitor for relapse cancer after treatment is needed.

All invasive cervix cancers release fragments into the blood which contain DNA. In HPV positive cancers these fragments from the cancer will contain HPV DNA. The presence of HPV DNA in the bloodstream can help researchers identify if a patient has any remaining cancer after the completion of their treatment. HPV-detect is a new test developed by researchers at The Royal Marsden Hospital (RMH) and The Institute of Cancer Research, London. HPV-detect has already been tested in a small study carried out at RMH in cervix cancer patients. The study showed that the HPV-detect test could detect HPV DNA (released from HPV positive tumours) in the bloodstream of more than 90% patients. The study also showed that patients with no HPV DNA in their blood after treatment did not relapse. This supports the accuracy of the HPV-detect test. However, further testing of HPV-detect in a larger study is needed. The aim of the TROPICCANA study is to find out if HPV-detect can accurately confirm that no disease remains after chemoradiotherapy and thus reassure patients with equivocal scans. The study will also assess whether HPV-detect can be used to detect relapse sooner than examination or imaging.

Who can participate?

Adults over the age of 18 years who are receiving chemoradiation for locally advanced cervix cancer.

What does the study involve?
TROPICCANA is a blood and tissue sample collection and data analysis study. It does not involve any additional screening tests, treatments or visits to the hospital. Participants will be asked to donate one blood sample before treatment and up to eight blood samples during treatment and follow-up. Participants will also be asked to donate the tumour sample that was collected from the cervix when they were diagnosed and any additional tissue samples that are routinely collected after their treatment.

What are the possible benefits and risks of participating?
This is a voluntary research study and will not be of direct benefit to those taking part but may prove to be of benefit to others in the future.
Participants will be required to give frequent blood samples that would not be required otherwise. Risks linked with collecting blood samples from an arm include pain from the needle being inserted, bruising, light-headedness, possible fainting, and (rarely) infection.

Where is the study run from?
The TROPICCANA study is being run by The Royal Marsden NHS Foundation Trust in the United Kingdom.

When is the study starting and how long is it expected to run for?
From January 2026 to July 2030

Who is funding the study?
Lady Garden Foundation and CRUK RM/ICR RadNet Centre

Who is the main contact?
Dr Susan Lalondrelle
Susan.Lalondrelle@rmh.nhs.uk

Lay summary under review with external organisation

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Dr Susan Lalondrelle

Contact details
The Royal Marsden NHS Foundation Trust
Oak Cancer Centre
16 Oakleaf Avenue
Sutton
United Kingdom
SM2 5GP
+44 20 8915 4143
Susan.Lalondrelle@rmh.nhs.uk

Type(s)
Public

Contact name
None Agnieszka Niebrzydowska

Contact details
The Royal Marsden NHS Foundation Trust
Oak Cancer Centre
16 Oakleaf Avenue
Sutton
United Kingdom
SM2 5GP
+44 20 8915 6666
Agnieszka.Niebrzydowska@rmh.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
310379

Study information

Scientific Title
Treatment Response In Cervix Cancer Assessed by circulating HPV DNA

Acronym
TROPICCANA

Study objectives
Primary objective:
Validation of cHPV-DNA, measured using ddPCR as a predictor of residual disease following primary chemoradiotherapy for locally advanced cervix cancer.

Secondary objectives:
1. To compare cHPV-DNA with MRI and PET-CT as a marker of residual disease
2. To assess if cHPV-DNA can be used to detect relapse during follow-up
3. To compare cHPV-DNA with MRI and PET-CT as a marker of disease relapse following successful treatment
4. To measure cHPV-DNA levels at baseline and during follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/01/2026, South Central - Oxford A REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; oxforda.rec@hra.nhs.uk), ref: 26/SC/0016

Primary study design
Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Patients with locally advanced cervix cancer receiving chemoradiation.

Interventions
TROPICCANA is a blood and tissue sample collection and data analysis study. It does not involve any additional screening tests, treatments or visits to the hospital. Participants will be asked to donate one blood sample before treatment and up to eight blood samples during treatment and follow-up. Participants will also be asked to donate the tumour sample that was collected from the cervix when they were diagnosed and any additional tissue samples that are routinely collected after their treatment.
Participants will receive standard of care treatment and follow-up. Participants will continue their clinical examinations and imaging as per standard of care. Disease status will be collected during follow-up up to 3 years.
Participants' treatment plans will not be altered based on the HPV-detect test results.

Intervention Type
Other

Primary outcome(s)
1. Specificity of cHPV-DNA measured using proportion of all patients confirmed negative for residual disease (diagnosed via imaging and clinical follow-up to 24 months) who have undetectable ctDNA levels at 3 months post-treatment, residual disease status confirmed by follow-up to 24 months post-treatment

Key secondary outcome(s))
1. Association between cHPV-DNA detection at each timepoint and disease status (recurrence /not recurrence) based on clinical examination at the same timepoint measured using proportion of patients with disease recurrence (diagnosed via clinical exam) at each timepoint, in patients grouped by ctDNA status (detected vs undetected) at 6 months, 9 months, 12 months, 18 months, and 24 months post-treatment.

2. Association between cHPV-DNA detection at each timepoint between 6 to 18 months, and the presence of any recorded disease recurrence from that timepoint up to 24 months post-treatment measured using proportion of patients with disease recurrence (diagnosed via imaging or clinical exam up to 24 months post-treatment) at each timepoint, in patients grouped by ctDNA status (detected vs undetected) at 6 months, 9 months, 12 months, 18 months post-treatment, residual disease status confirmed by follow-up to 24 months post-treatment.

3. Association between cHPV-DNA detection at 24 months, and the presence of any recorded disease recurrence from that timepoint up to 3 years post-treatment measured using proportion of patients with disease recurrence (diagnosed via imaging or clinical exam up to 36 months post-treatment), in patients grouped by ctDNA status at 24 months post-treatment (detected vs undetected) at 24 months post-treatment, residual disease status confirmed by follow-up to 36 months post-treatment

4. Sensitivity and specificity of cHPV-DNA levels compared to tissue HPV tissue status at baseline and during follow-up measured using proportion of patients with disease recurrence

(diagnosed via imaging or clinical exam up to 24 months post-treatment) at each timepoint, in patients grouped by tissue HPV status (positive vs negative) at 3 months, 6 months, 9 months, 12 months, and 18 months post-treatment

Completion date
30/07/2030

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Patients with histologically confirmed Stage 1B-4A (FIGO 2018) histologically confirmed HPV associated carcinoma of the cervix
3. Planned to receive radical radiotherapy or chemoradiotherapy
4. Treatment and follow-up within the same hospital or centre
5. Ability to give informed consent for biological sample collection

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previous or concurrent illness or situation, which in the investigator’s opinion would interfere with completion of the sample collection
2. Any invasive malignancy within the previous 2 years (other than non-melanomatous skin carcinoma or cervical carcinoma in situ)

Date of first enrolment
30/01/2026

Date of final enrolment
30/07/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
England
SW3 6JJ

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type

Funder Name
Lady Garden Foundation

Funder Name
RadNet at The Institute of Cancer Research and The Royal Marsden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available