

# Collection of cervical cells at colposcopy using a novel technique for analysis of high-risk vs low-risk lesions

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<b>Registration date</b> 14/09/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/03/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The aim of this study is to improve the collection and analysis of cells taken from the surface of the cervix (neck of the womb) in order to more accurately identify cervical disease when it is present.

### Who can participate?

Women aged 25 to 65 years with screen-detected abnormal cervical cytology varying from mild dyskaryosis to severe dyskaryosis (change of appearance in cells that cover the surface of the cervix)

### What does the study involve?

Cells taken from the surface of the cervix are currently sampled using a cytobrush or spatula as part of the cervical smear test. This approach scrapes and/or scarifies the surface of the cervix and harvests a mixture of cells from the superficial to mid epithelial layers. The researchers propose a modified approach in which cells are taken from the surface of the cervix using a 'filter paper disk of nylon or cellulose. In the modified approach, the disk of nylon or cellulose will be gently pressed onto the surface of the cervix in order to lift off a layer of exfoliating surface cells. The morphology (shape, structure, form, and size) of the surface cells is indicative of underlying cervical disease, and this can then be assessed by cytological analysis.

### What are the possible benefits and risks of participating?

There are no immediate clinical benefits in this study but the information obtained could be used to better inform which women may need treatment in the future. Apart from a slightly longer procedure (less than 5 minutes), there are no risks in taking part.

### Where is the study run from?

Addenbrookes Hospital (UK)

### When is the study starting and how long is it expected to run for?

June 2017 to July 2026

Who is funding the study?  
Cancer Research UK

Who is the main contact?  
Dr Robin Crawford, robin.crawford@nhs.net

## Contact information

### Type(s)

Scientific

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**Additional identifiers**

**Integrated Research Application System (IRAS)**

224794

**Central Portfolio Management System (CPMS)**

## Study information

### Scientific Title

Collection of cervical cells at colposcopy using a novel technique for analysis of high-risk vs low-risk lesions

### Acronym

CCL Cancer cell lift

### Study objectives

The aim of the project is to improve the collection and analysis of cells taken from the surface of the cervix in order to identify more accurately high-risk cervical pathology when it is present. Patients attending colposcopy who are undergoing assessment for an abnormal smear will be asked to take part. At the start of the examination, a photograph of the cervix will be taken. Then a disc of material (nitrocellulose) designed to collect cells will be applied to the cervix for 15 seconds and then removed and fixed for analysis. There are a number of potential advantages:

1. Reduced need for biopsy
2. Aid localisation of high-risk vs low-risk lesions
3. Ultimately lead to more patient-focused treatment with a reduction in the need for Loop treatments and thus reducing the morbidity associated with this

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 04/05/2017, Oxford B Ethics Committee, South Central Region (South Central – Oxford B Research Ethics Committee, Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8046; oxfordb.rec@hra.nhs.uk), REC ref: 17/SC/02

### Study design

Non-randomized; Both; Design type: Screening, Active Monitoring, Clinical Laboratory Study

### Primary study design

Interventional

### Study type(s)

Diagnostic

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

Cervical cancer

### Interventions

The patient will be invited to take part in the study. The woman will have been informed that there is an active research programme in the colposcopy clinic. Following consent with the study nurse, the patient will discuss her case with the colposcopist.

When the woman is ready for the colposcopy, a digital photograph of the cervix will be taken after the removal of the cervical mucus with a cotton bud (takes less than 10 seconds the system is set up to take colpophotographs). The filter disc is applied to the surface of the cervix for 15 seconds with mild pressure (no discomfort for the patient). The disc is removed and stored in transport medium. The standard colposcopic examination then begins with the application of an acetic acid solution. A further colpophotograph is taken. Biopsies or treatment as per the underlying disease are performed as required. Correlation between the two photographs, the colposcopist's opinion and the histology will be made with the disc. The researchers aim to recruit 2-3 patients per week and aim for a mixture of patients with referral for high-grade and low-grade abnormalities.

### **Intervention Type**

Other

### **Primary outcome(s)**

Correlation between high-risk and low-risk cervical disease identified using the filter disc and by the standard method

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

31/07/2026

## **Eligibility**

### **Key inclusion criteria**

1. Participant is willing and able to give informed consent for participation in the study
2. Female, aged 25 years or above
3. Diagnosed with abnormal cervical cytology by routine screening

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

25 years

### **Upper age limit**

100 years

### **Sex**

Female

**Total final enrolment**

764

**Key exclusion criteria**

1. Participant is unable to give consent
2. Pregnant
3. HIV/systemic Immunosuppression

**Date of first enrolment**

12/10/2017

**Date of final enrolment**

30/04/2022

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

United Kingdom

England

**Study participating centre****Addenbrookes Hospital**

Hills Road

Cambridge

England

CB2 0QQ

**Sponsor information****Organisation**

Cambridge University Hospitals NHS Foundation Trust

**ROR**

<https://ror.org/04v54gj93>

**Funder(s)****Funder type**

Charity

**Funder Name**

Cancer Research UK; Grant Codes: C25663/A28754

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Data sharing statement to be made available at a later date

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 7	21/02/2022	11/04/2022	No	No