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

Submission date 07/04/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/09/2021	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 22/05/2025	**Condition category** Cancer	[_] Individual participant data [X] 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 March 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

EudraCT/CTIS number
Nil known

IRAS number

224794

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44798, IRAS 224794

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please contact the study coordinator to request a participant information sheet.

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
07/06/2017

Completion date
31/03/2026

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

Age group
Adult

Lower age limit
25 Years

Sex
Female

Target number of participants
Planned Sample Size: 387; UK Sample Size: 387

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
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
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Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Additional files are not available to upload but please contact the study coordinator to request the protocol if necessary. Planned publication in a high-impact peer-reviewed journal in 2022 /2023.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

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?
Protocol file	version 7	21/02/2022	11/04/2022	No	No
HRA research summary			28/06/2023	No	No