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Monitoring of precancerous cervical lesions at colposcopy using a new non-invasive technique

Submission date
13/04/2021

Recruitment status
No longer recruiting

Registration date
27/01/2022

Overall study status
Completed

Last Edited
15/01/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
This study is being done to improve the management of women diagnosed with cervical intraepithelial neoplasia grade 2 (CIN2). Cervical intraepithelial neoplasia is a precancerous condition where abnormal cells grow on the surface of the cervix. CIN 2 means two-thirds of the thickness of the cervical surface layer is affected by abnormal cells. In the past this condition was treated by removal of the disease. However, as we have learnt more about this condition we now know that the majority of these cases resolve spontaneously. This has meant that these women can be offered a watchful waiting approach/expectant management approach. Indeed there has been much work that has now led to clinicians advocating for conservative management. A new non-invasive approach enables doctors to monitor these lesions at a molecular level without the need for a biopsy (tissue sample). This means that such women can be effectively managed in the community without the requirement for an intrusive exam/test.

Who can participate?
Female patients with more than moderate dyskaryosis (change of appearance of the cells that cover the surface of the cervix), between 25 and 35 years of age, with confirmed CIN2 in a single quadrant of the cervix

What does the study involve?
One baseline and up to four further colposcopic examinations during the course of the year. Colposcopy is a procedure to visually examine the cervix using a colposcope. This is one or two additional follow-up examinations in comparison to the normal 6 monthly follow-up appointments for patients who are currently having conservative management for CIN2.

What are the possible benefits and risks of participating?
There are no immediate clinical benefits in this study but the information collected could be used to help decide which women may need treatment in the future. The main disadvantage is a slightly longer procedure (less than 5 minutes) and the two extra visits to the colposcopy clinic for a colposcopic exam. The nitrocellulose absorbent paper is made of material that is perfectly safe to use in humans. There are no other risks in taking part.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust, Addenbrookes Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2020 to December 2022

Who is funding the study?
The British Society For Colposcopy and Cervical Pathology (BSCCP) (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272534

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44602, IRAS 272534

Study information

Scientific Title
Monitoring of cervical lesions at colposcopy using a novel non-invasive technique for monitoring of CIN2 lesions (a pilot/feasibility study)

Study objectives

The purpose of this study is to examine how best to treat a condition called cervical intraepithelial neoplasia, which is also referred to as CIN2, and is a condition that exists before fully developed cancer cells are formed. The plan is to assess the feasibility of treating CIN2 with watchful waiting rather than surgical treatment. Currently, patients diagnosed with CIN2 are offered the choice of watching and waiting to see what happens as there is more than a 50% chance that the condition will resolve itself without any intervention being necessary. However, up till now, there is no effective way to monitor this condition that isn't invasive. To improve the way we keep an eye on how this condition is developing, or not, we have a new approach. We plan to offer patients the opportunity to have the top few cells lifted onto a small piece of nitrocellulose paper. This procedure is called cervical cell lift. In the laboratory, technicians are able to analyse the cell lifts so that the cells can be examined in a way that is as near as how they would look inside the body. This approach of keeping the cells together in their natural relationship to other cells on the cervix may be more useful than looking at individual cells. Researchers think this method of examining a cervical cell sample (called a 'template') may improve the way they are able to diagnose a patient's condition and monitor whether it is getting better or worse in a more meaningful way.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2020, East of England Cambridge & Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)20 797 22545; cambsandherts.rec@hra.nhs.uk), REC ref: 20/EE/0082

Study design
Non-randomized; Both; Design type: Screening, Cellular, Management of Care, Active Monitoring, Clinical Laboratory Study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cervical intraepithelial neoplasia [CIN], grade II

Interventions
If enrolled on the study after CIN2 diagnosis:
1. Primary visit for colposcopy – CIN2 identified, acetowhite photograph and Patch taken followed by biopsy
2. 3-month visit for colposcopy – Patch, acetowhite photograph taken and colposcopy done to ensure no change in lesion and comparison with previous photograph of acetowhite change
3. 6-month visit for colposcopy - Patch, acetowhite photograph taken and colposcopy done to ensure no change in lesion and comparison with previous photograph of acetowhite change
4. 9-month visit for colposcopy - Patch, acetowhite photograph taken and colposcopy done to ensure no change in lesion and comparison with previous photograph of acetowhite change
5. 1-year visit for colposcopy – Patch, acetowhite photograph taken and either further biopsy or excisional treatment as per colposcopist impression

If enrolled on the study from the pre-existing clinical pathway, participants will start the study at either the 3-month visit (-/+ 2 weeks) or the 6-month routine clinical visit (-/+ 2 weeks) following CIN2 diagnosis.

Intervention Type
Other

Primary outcome(s)
1. CIN2 lesions identified using colposcopy/cytology/histology and cell lift at 0 months (colposcopy cell lift and biopsy), 3 months (colposcopy and cell lift), 6 months (colposcopy, cytology and cell lift), 9 months (colposcopy and cell lift), and 12 months colposcopy cell lift and biopsy)
2. Biomarker patterns consistent with lesion regression/progression identified using immunohistochemistry at 0, 3, 6, 9 and 12 months

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2022

Eligibility

Key inclusion criteria
All patients who are <35 years of age AND are CIN2 positive on biopsy AND have only single quadrant disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Upper age limit
35 years

Sex
Female

Total final enrolment
14

Key exclusion criteria
1. Patients >35 years
2. Patients who are pregnant

3. Patients who are immunosuppressed/are HIV positive
4. Patients who cannot give informed consent
5. Patients who are allergic to nail varnish/have been told they are allergic to nitrocellulose

Date of first enrolment
07/04/2021

Date of final enrolment
24/08/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Hills Road
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Other

Funder Name
British Society for Colposcopy and Cervical Pathology

Alternative Name(s)
BSCCP

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

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?
HRA research summary			26/07/2023	No	No
Protocol file	version 4	21/01/2022	11/04/2022	No	No