

Randomized trial of immediate treatment versus colposcopic followup for biopsy-proven cervical intraepithelial neoplasia (CIN) 1

Submission date 26/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/04/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MCT-38135

Study information

Scientific Title

Randomized trial of immediate treatment versus colposcopic followup for biopsy-proven cervical intraepithelial neoplasia (CIN) 1

Study objectives

The optimal management strategy for women with biopsy confirmed Cervical Intraepithelial Neoplasia 1 (CIN 1) is unclear. Our hypothesis is that a strategy of colposcopic follow up and treating progressive disease is as good as immediate treatment with Loop Electrosurgical Excision Procedure (LEEP).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the McMaster University Research Ethics Board in December 2004.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Preinvasive Cervical Disease

Interventions

1. Colposcopic Follow up for 18 months
2. Immediate LEEP treatment

Trial details received: 12 Sept 2005

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Progression to CIN 2 or worse within 18 months.

Key secondary outcome(s)

1. Persistent CIN 1 at 18 months
2. Adverse events
3. Assess the following prognostic factors: persistent versus incident disease, lesion size, patient s age, smoking, Human Papillomavirus (HPV) type and load

Completion date

30/09/2007

Eligibility

Key inclusion criteria

1. Documented CIN 1 by histologic assessment as the highest grade lesion present
2. Lesion confined to the cervix and completely visualized
3. Be 16 years or older, female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

415

Key exclusion criteria

Among patients satisfying the inclusion criteria the following will be excluding characteristics:

1. Index Pap smear showing CIN 2, 3 or cancer:
 - 1.1. Index Pap smear shows atypical glandular cells of unknown significance, glandular dysplasia or malignancy requiring immediate investigation
 - 1.2. Patients with previously identified CIN 1 by biopsy who are already in a surveillance program
2. Unsatisfactory colposcopic exam defined as inability to see the extent of the lesion in the endocervical canal or absence of a lesion on the ectocervix but endocervical curettage shows CIN 1
3. Pregnancy
4. Prior therapy for dysplasia including medical (5FU), surgical (Laser, LEEP) or cryotherapy
5. Prior gynecologic cancer
6. Prior pelvic radiation therapy
7. Inability to attend outpatient followup visits because of geographic inaccessibility
8. Other malignancies except non-melanoma skin cancer
9. Immunosuppression due to diseases such as Acquired Immune Deficiency Syndrome (AIDS), organ transplantation, or on immunosuppressive medications such as prednisone, imuran or chemotherapy for diseases like systemic lupus
10. Cognitively impaired or otherwise unable to obtain written informed consent
11. Extension of the CIN 1 lesion to vagina or a separate vaginal lesion showing dysplasia
12. Colposcopically visible condyloma outside of the transformation zone
13. Known allergy to local analgesics
14. Clinically evident vaginitis must be treated and resolved prior to entry on the trial
15. Inability to read and respond in English
16. Failure to provide informed consent

Date of first enrolment

01/11/2000

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Canada

Study participating centre

Juravinski Cancer Centre

Hamilton

Canada

L8V 5C2

Sponsor information

Organisation

McMaster University (Canada) - Faculty of Health Sciences

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-38135)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2011	12/04/2021	Yes	No