ISRCTN91252554 https://doi.org/10.1186/ISRCTN91252554

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/09/2005	**Overall study status** Completed	
Last Edited 12/04/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lorraine Elit

Contact details
Juravinski Cancer Centre
Division of Gynecologic Oncology
699 Concession Street
Hamilton
Canada
L8V 5C2
+1 905 389 5688
laurie.elit@hrcc.on.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Progression to CIN 2 or worse within 18 months.

Secondary outcome measures
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

Overall study start date
01/11/2000

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

Age group
Adult

Sex
Female

Target number of participants
884

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

Sponsor details
c/o Ms. Marie Townsend
Administrator, Research Programs
Office of the Associate Dean
1200 Main St. W., Room HSC-3N8
Hamilton
Canada

L8N 3Z5
+1 905 525 9140 ext. 22465
hsresadm@mcmaster.ca

Sponsor type
University/education

Website
http://www.mcmaster.ca/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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