

Effective haemostasis following a cervical punch biopsy: a randomised controlled study

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/03/2014	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544160622

Study information

Scientific Title

Study objectives

The main objective is to improve practice methods that are evidence based, in order to give women who are referred to the colposcopy department the highest standard of care. Those women that undergo a small biopsy of the cervix to obtain histological diagnosis following an abnormal cervical smear require the use of cautery to the area to stop bleeding. This study aims to demonstrate which method is better for the patient as far as speed and follow-up vaginal discharge and/or bleeding. The outcome from the data will ensure that best practice is maintained within the colposcopy clinical setting.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Cervical punch biopsy

Interventions

Women with mild smears will be sent study information and "Coming for a Colposcopy" leaflet. They will be seen in the colposcopy clinic and, following consultation and consent, women will be colposcoped. If colposcopically the cervix appears to have low grade changes then a biopsy /biopsies will be taken.

They will then be randomly allocated into either the silver nitrate or Monsel's solution group to obtain haemostasis.

The process of cautery will be timed using a stop watch from initial contact of the cauterising agent until haemostasis is obtained.

The women will be asked to keep a record of their discharge and if acceptable will be telephoned one week post procedure to ask about their findings. If the women prefer not to be contacted by phone or are not obtainable on the phone then a follow-up sheet will be given to them with a pre-paid envelope for them to send it in.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

The primary outcome is the length of time taken to obtain haemostasis following a cervical punch biopsy

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2005

Completion date

01/01/2007

Eligibility**Key inclusion criteria**

To ensure that a representative sample is taken from women in the Cambridge area who are referred to the colposcopy clinic with a mildly abnormal cervical smear, consecutive women from the referral list will be sent the study information leaflet. The referral list is obtained from the colposcopy data base and consists of women that have abnormal smears requiring colposcopy referred from the cytology laboratory. The list is random in that it is not in order of age, name or severity of smear.

Participant type(s)

Patient

Age group

Not Specified

Sex

Female

Target number of participants

30 participants in each of the two groups

Key exclusion criteria

Women will be excluded from the study if they are pregnant, have a known infection or are on anti-coagulation therapy.

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Dept of Colposcopy**

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

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SW1A 2NL

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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (UK), NHS R&D Support Funding

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