ISRCTN20662379 https://doi.org/10.1186/ISRCTN20662379

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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 13/03/2014	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Kay Welton

Contact details
Dept of Colposcopy
Box 224
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)

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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

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
United Kingdom

England

Study participating centre
Dept of Colposcopy
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration