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

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

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

**Type(s)** Scientific

**Contact name** Ms Kay Welton

## Contact details

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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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

**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