

Comparative study of local anaesthesia, forced coughing and no anaesthesia for pain reduction in colposcopically directed cervical punch biopsies

Submission date 08/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 09/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/11/2009	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

Study information

Scientific Title
Comparative study of local anaesthesia, forced coughing and no anaesthesia for pain reduction in colposcopically directed cervical punch biopsies: a randomised trial

Study objectives

Is there any differences between local anaesthesia, forced coughing and no local anaesthesia for pain reduction in cervical punch biopsies?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Dr. Lutfi Kirdar Kartal Research and Training Hospital approved on the 26th March 2009 (ref: 18/28.05.2009)

Primary study design

Interventional

Study design

Randomised controlled single centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Abnormal pap smear/cervical punch biopsy

Interventions

Please note that as of 24/11/09, the end date of this trial had been extended from 01/09/09 to 01/12/09.

This trial is taking place at the Istanbul Dr. Lutfi Kirdar Kartal Research and Training Hospital, Department of Obstetrics and Gynaecology. Approximately 114 patients will be recruited, 38 patients in each of the following three groups:

1. Local anaesthesia with lidocaine
2. Forced coughing
3. No local anaesthesia

Patient allocation will be carried out as follows:

A computer based randomisation will be prepared. The anaesthesia type will be printed on identical sheets of paper, which will be put into identical, consecutively numbered sealed opaque envelopes by a non-participating colleague.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Pain score when the first biopsy performed

Key secondary outcome(s)

Pain score for overall procedure

Completion date

01/12/2009

Eligibility

Key inclusion criteria

1. Women between ages of 18 - 65 years
2. Abnormal pap smears indicated cervical punch biopsy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Female

Key exclusion criteria

1. Any contraindications for parenteral analgesics
2. Any contraindications for lidocaine
3. Pregnancy

Date of first enrolment

01/06/2009

Date of final enrolment

01/12/2009

Locations

Countries of recruitment

Türkiye

Study participating centre

Cihat Saran Sk. Cagdas Apt. No:11/3

Istanbul

Türkiye

34841

Sponsor information

Organisation

Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey)

ROR

<https://ror.org/01c2wzp81>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Dr. Lutfi Kirdar Kartal Research and Training Hospital (Turkey) - Department of Obstetrics and Gynaecology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration