

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

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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## 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)

### Study design

Randomised controlled single centre trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure**

Pain score when the first biopsy performed

**Secondary outcome measures**

Pain score for overall procedure

**Overall study start date**

01/06/2009

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Female

**Target number of participants**

Approximately 114

**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)

**Sponsor details**

c/o M. Murat Naki

Department of Obstetrics and Gynaecology

Istanbul

Türkiye

34841

**Sponsor type**

Hospital/treatment centre

**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**

**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